MedSun: Newsletter #41, October 2009

Articles

Medtronic Neuromodulation, INDURA 1P Intrathecal Catheter, Intrathecal Catheter, Sutureless Pump Connector Revision Kit, and Intrathecal Catheter Pump Segment Revision Kit

Print Item
E–mail Item

FDA MedWatch Safety Alert

FDA notified healthcare professionals of the Class 1 recall of Medtronic SC Catheters and Revision Kit Models: 8709SC, 8731SC, 8578, and 8596SC when paired with the Medtronic IsoMed Pump Model 8472, due to a design incompatibility resulting in a physical interference between the SC catheter connector and the IsoMed pump. This may prevent the SC catheter from completely connecting to the IsoMed pump, even though it may appear to be connected and feel secure and may lead to disruptions of therapy and revision surgery, which pose a risk of serious injury or death.

Additional Information:

FDA MedWatch Safety Alert. Medtronic Neuromodulation, INDURA 1P Intrathecal Catheter, Intrathecal Catheter, Sutureless Pump Connector Revision Kit, and Intrathecal Catheter Pump Segment Revision Kit. September 24, 2009. http://www.fda.gov/Safety/MedWatch/SafetyInformation/SafetyAlertsforHumanMedicalProducts/ucm183753.htm[7]

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LIFEPAK CR Plus Automated External Defibrillators (Physio-Control, Inc)

Print Item
E–mail Item

FDA MedWatch Safety Alert

FDA notified healthcare professionals of a Class I recall of certain LIFEPAK CR Plus Automated External Defibrillators (AED) manufactured and distributed from July 9, 2008 through August 19, 2008. An extremely humid environment may cause the affected devices to improperly analyze the heart rhythm and may cause the device to delay or fail to deliver therapy.

Additional Information:

FDA MedWatch Safety Alert. LIFEPAK CR Plus Automated External Defibrillators (Physio-Control, Inc). September 16, 2009.
http://www.fda.gov/Safety/MedWatch/SafetyInformation/SafetyAlertsforHumanMedicalProducts/ucm182496.htm[9]

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Class I Recall of Covidien Pedi-Cap End-Tidal CO2 Detector

Print Item
E–mail Item

FDA MedWatch Safety Alert

Affected Pedi-Cap and Pedi-Cap 6 devices may increase the resistance of the flow of air into the lungs, resulting in ineffective ventilation and the inability to verify the correct placement of a breathing tube when inserting it into the windpipe. Covidien informed their distributors and customers to stop selling/using the affected devices and to return them to the company.

Additional Information:

FDA MedWatch Safety Alert. Covidien Pedi-Cap End-Tidal CO2 Detector. September 10, 2009.
http://www.fda.gov/Safety/MedWatch/SafetyInformation/SafetyAlertsforHumanMedicalProducts/ucm181878.htm[11]

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Class I Recall of ConMed Linvatec - Universal Cables and Power Pro Handpieces

Print Item
E–mail Item

FDA MedWatch Safety Alert

Two ConMed Linvatec surgical service products due to reports of a switch problem resulting in unintended self-activation of these powered tools, continued running after trigger release and tool movement in unintended directions. The handpieces were distributed from March 29, 2002 through June 24, 2009. The cables were distributed from January 24, 2001 through February 27, 2009. ConMed has instructed users to stop using the cable immediately if the handpiece self-activates or an intermittent operation occurs and to return the handpiece and cable to the company for evaluation.

Additional Information:

FDA MedWatch Safety Alert. ConMed Linvatec - Universal Cables and Power Pro Handpieces. September 10, 2009.
http://www.fda.gov/Safety/MedWatch/SafetyInformation/SafetyAlertsforHumanMedicalProducts/ucm181833.htm[13]

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Class I Recall of Penumbra Neuron 5F Select Catheter

Print Item
E–mail Item

FDA MedWatch Safety Alert

Due to a manufacturing error, the Penumbra Neuron 5F Select catheter may contain pin holes and exposed wire braids which may result in a brain clot or a blood vessel puncture, and this may lead to possible death.

Additional Information:

FDA MedWatch Safety Alert. Penumbra Neuron 5F Select Catheter. September 9, 2009. http://www.fda.gov/Safety/MedWatch/SafetyInformation/SafetyAlertsforHumanMedicalProducts/ucm181725.htm[15]

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The Joint Commission Alert: Effective Leadership Critical to Preventing Medical Errors

Print Item
E–mail Item

The Joint Commission News Releases
Health care leaders are urged to step up efforts to prevent errors by taking the zero-defect approach used in other high-isk industries such as aviation and nuclear energy. To improve patient safety, The Joint Commission's Sentinel Event Alert recommends that the governing body, chief executive officer, senior managers and medical staff leaders at health care organizations take a series of 14 specific steps found in this article.

Additional Information:

The Joint Commission Alert: Effective Leadership Critical to Preventing Medical Errors. The Joint Commission News Releases. August 27, 2009. http://www.jointcommission.org/NewsRoom/NewsReleases/nr_8_27_09.htm[17]

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H1N1 Resources from FDA and CDC

Print Item
E–mail Item

The following resources from FDA and CDC include information on recent H1N1 vaccine approvals, H1N1 vaccination recommendations, proper use of facemasks and respirators, and tips on preventing and controlling the seasonal flu.

Additional Information:

FDA Approves Vaccines for 2009 H1N1 Influenza Virus. FDA Press Release. September 15, 2009.
http://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm182399.htm[19]

Novel H1N1 Vaccination Recommendations. CDC website. September 11, 2009.
http://www.cdc.gov/h1n1flu/vaccination/acip.htm[20]

Use of Influenza A (H1N1) 2009 Monovalent Vaccine: Recommendations of the Advisory Committee on Immunization Practices (ACIP), 2009. CDC MMWR. August 21, 2009.
http://www.cdc.gov/mmwr/preview/mmwrhtml/rr58e0821a1.htm[21]

CDC's Interim Recommendations for Facemask and Respirator Use to Reduce Novel Influenza: A (H1N1) Virus Transmission. August 5, 2009.
http://www.cdc.gov/h1n1flu/masks.htm[22]

Prevention and Control of Seasonal Influenza with Vaccines. CDC MMWR. July 24, 2009.
http://www.cdc.gov/mmwr/preview/mmwrhtml/rr58e0724a1.htm?s_cid=rr58e0724a1_e[23]

CDC Advisors Make Recommendations for Use of Vaccine Against Novel H1N1. CDC press release. July 29, 2009.
http://www.cdc.gov/media/pressrel/2009/r090729b.htm[24]

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Pregnancy Increases Risk of Severe H1N1 Disease

Print Item
E–mail Item

MedPage Today

Pregnant women are at greater risk for severe disease and complications from H1N1 pandemic flu than the general public. They should be treated promptly with antiviral drugs if the pandemic flu strain is suspected. This recommendation is based on an analysis of cases and deaths of pregnant women from the pandemic strain in the early weeks of the U.S. outbreak. Doctors treating pregnant women should also have a triage system to screen for influenza-like symptoms.

Additional Information:

Pregnancy Increases Risk of Sever H1N1 Disease. MedPage Today. July 29, 2009.
http://www.medpagetoday.com/InfectiousDisease/SwineFlu/15284[26]

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LabNet

Interim Guidance for the Detection of Novel Influenza A Virus Using Rapid Influenza Diagnostic Tests

Print Item
E–mail Item

CDC

This interim guidance provides an overview of the sensitivities of rapid influenza diagnostic tests (RIDT) in detecting novel influenza A (H1N1) virus in order to help guide the reporting and interpretation of test results. This document does not discuss either direct (DFA) or indirect immunofluorescence assays (IFA). This guidance is primarily intended for clinical laboratories and clinical practices conducting influenza testing on respiratory specimens from patients with suspected novel influenza A (H1N1) virus infection.

Additional Information:

Interim Guidance for the Detection of Novel Influenza A Virus Using Rapid Influenza Diagnostic Tests. CDC website. August 10, 2009.
http://www.cdc.gov/h1n1flu/guidance/rapid_testing.htm[28]

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H1N1 Resources from FDA and CDC

Print Item
E–mail Item

Please see the article titled, 'H1N1 Resources from FDA and CDC' posted in this month's MedSun Newsletter.

Additional Information:

MedSun Newsletter. October 2009. H1N1 Resources from FDA and CDC.
http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/medsun/news/newsletter.cfm?news=41#7[30]

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HomeNet

Buying Medical Devices and Diagnostic Tests Online - FDA

Print Item
E–mail Item

FDA

Buying online has advantages, but it also can produce pitfalls for some consumers. The Internet offers many quality medical devices from legitimate sites. It also offers medical devices that don't work and some that may even harm you or your family. Some Web sites sell medical devices for unapproved uses, or they sell medical devices that have not been cleared or approved by FDA. This article provides tips on how to safely purchase devices on the internet.

Additional Information:

Buying Medical Devices and Diagnostic Tests Online. FDA website. June 26, 2009. http://www.fda.gov/MedicalDevices/ResourcesforYou/Consumers/BuyingMedicalDevicesandDiagnosticTestsOnline/default.htm[32]

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KidNet

Portex Uncuffed Pediatric-Sized Tracheal Tubes (sizes 2.5, 3.0 and 3.5 mm)

Print Item
E–mail Item

FDA MedWatch Safety Alert

Smiths Medical and FDA notified healthcare professionals about a nationwide voluntary recall of Portex Uncuffed Pediatric-Sized Tracheal Tubes (sizes 2.5, 3.0 and 3.5 mm). A small number of tubes were manufactured with internal diameters slightly smaller than indicated on the labeling, which may create the potential for the clinician to experience difficulty passing through or withdrawing the suction catheter.

Additional Information:

FDA MedWatch Safety Alert. Portex Uncuffed Pediatric-Sized Tracheal Tubes (sizes 2.5, 3.0 and 3.5 mm). Updated September 21, 2009. http://www.fda.gov/Safety/MedWatch/SafetyInformation/SafetyAlertsforHumanMedicalProducts/ucm182084.htm[34]

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Highlighted MedSun Reports

Highlighted Reports

Print Item
E–mail Item

This section contains a sample of reports from all the MedSun reports received during a particular period. The reports were submitted by MedSun Representatives. In some instances the reports have been summarized and/or edited for clarity. The entries that follow represent a cross section of device-related events submitted by MedSun reporters during the period July 1 through July 31. All other reports can be searched under the 'MedSun reports' menu pane. Note: the two month delay is due to quality control and follow-up.

ANESTHESIOLOGY

Device:

Type: Lumbar puncture tray
Manufacturer: Busse Inc..
Brand: Safety lumbar puncture tray
Model#: na
Lot #: 0810006 D
Cat #: 949
Other #: CE #0086

Problem:
Nursing staff noted that there is no filter needle in the lumbar puncture tray, although the kit does contain an ampule of lidocaine intended for injection. When asking a physician who uses the tray routinely, the MD replied that he draws up the med from the ampule and injects it without using a filter needle. He typically uses this particular lumbar puncture tray, which does not have a filter needle included, but would prefer to use a filter needle when drawing the lidocaine. The nursing staff now includes a separately purchased filter needle for him when they provide him the tools for the procedure. The hospital must continually educate the new nursing staff to include a filter needle for the MD when using this lumbar puncture tray.

Of note, the labeling on the tray has the phrase "includes safety components" in large, italicized, circled font. Lippincott Nursing Practice Manual and the American Journal of Nursing both cite that the standard of care when drawing up medication from an ampule for injection is to use a filter needle. Staff recommends that the manufacturer include a filter needle in the kit, especially since it is advertised on the packaging front to contain safety components.

Manufacturer response (as per reporter) for lumbar puncture tray, Safety lumbar puncture tray:
A copy of this report has been faxed to the manufacturer

Device:

Type: Disposable Bacterial/viral Filter For Ventilator
Manufacturer: Ventlab Corp.
Brand: Guardian
Model#: FH 603003
Lot #: None listed
Cat #: FH603003
Other #: 22 mm OD/15 mm ID x 22 mm ID/15 mm OD

Problem:
New filter (Guardian disposable Bacterial/Viral filter) connected to expiratory hose of ventilator. Patient was placed on ventilator and started coughing very hard. Patient was removed from ventilator and hand bagged. There was no injury to patient.

Ventilator was later tested with an artificial lung. Artificial lung hyperinflated. No deflation. The filter was examined and it was found that the port (it's supposed to be hollow with openings at both ends for air flow) was completely sealed with clear rigid plastic at the distal end of the port. There was no opening to the distal end of the port. No way for air to flow through.

Manufacturer contacted our facility.

Device 1:

Type: Ventilator, High Frequency Oscillatory
Manufacturer: Care Fusion Healthcare Cardinal Health
Brand: Sensormedics 3100b
Model#: 3100 B
Lot #: NA
Cat #: NA
Other #: NA

Device 2:
Type: High Frequency Flexible Circuit
Manufacturer: Care Fusion Healthcare Cardinal Health
Brand: Sensormedics 3100b Flexible Breathing Circuit
Model#: NA
Lot #: 050409 (x3)
Cat #: 16390-102
Other #: NA

Problem:
HFOV circuit was not staying together and was frequently coming apart. This site of the disconnection was at the T-piece between the red and green valves. Circuit humidified water was leaking and MAP's unable to stay as set due to loose connection. HFOV vent and circuit were switched to a new one. Defective circuit was taken to Biomed.

Biomed analysis revealed the control cap popped off during installation. In addition, the tee adapter between dumb cap/diaphragm housing and control cap/diaphragm housing popped off during circuit install. No stress placed on the area during install.

See device images


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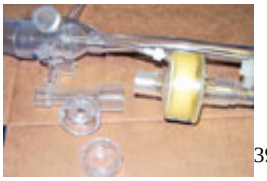
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Device:

Type: Pulse Oximeter
Manufacturer: GE Medical Systems, LLC
Brand: Tru-sat
Model#: OXY-MC3
Lot #: 28008
Cat #: OXY-MC3
Other #: (not provided)

Problem:
Patient cable that connects probe to Pulse Oximeter failed.

Manufacturer response (as per reporter) for Pulse Oximeter, Tru-Sat:

Manufacturer insists that the cables are meeting expected life span, however, we know of no information that is currently given to patient (in operator's manual) that suggests these need to be replaced periodically or on a routine basis. This results in replacement only after device fails which is dangerous based upon the sensitive nature and intent of this product.

CARDIOVASCULAR

Device:

Type: Monitor, Physiological
Manufacturer: Philips Medical Systems
Brand: MP70
Model#: MP70
Lot #: (not provided)
Cat #: (not provided)
Other #: M8007A

Problem:
A nurse was making an adjustment to the monitor position when she placed the palm of her hand against the bottom of the monitor screen to push the screen height up for visibility. When the monitor tipped off of the bracket that was attached to a movable arm, the monitor fell on its side onto the counter top below. The nurse was unwary her palm was against the monitor release button. No harm to staff or patient, on this event.

Manufacturer response (as per reporter) for Monitor, Physiological, MP70:
Manufacturer had educated staff about release button on the front of the monitor when the monitors where installed. After the event the manufacturer informed hospital about a safety latch assembles that will prevent premature separation from bracket arm, but was not offered to facility at time of monitor purchase.

The release latch for monitor is located on the front of the monitor, and only needs to be depressed 1/8" for the monitor to separate from the mounting arm bracket. The button on the monitor appeared to be just a design in the monitor casing. No labels or warning noted on the release button. For safety reason the button should have had a warning label that flags the user, not to push against the release button. The manufacturer needs to address this issue of safety and the potential of harm or injury, to both the user and patient.

Device:

Type: Cardiac Electrophysiology Mapping System
Manufacturer: Biosense Webster
Brand: Carto Xp
Model#: M-4700-96

Lot #: (not provided)
Cat #: (not provided)
Other #: (not provided)

Problem:
Carto has an issue with their equipment in one of our EP labs. When creating a map using Carto the map itself will shift on its own. At first it seems as if the patient has moved when in actuality it is a glitch in the Carto system. This has happened multiple times in this particular lab.

Device:

Type: Catheter, Ablation
Manufacturer: St. Jude Medical
Brand: Safire Tx
Model#: 402840
Lot #: (not provided)
Cat #: (not provided)
Other #: (not provided)

Problem:
The staff reports that the physician was using the Safire ablation catheter. When maneuvering the device, the physician said that the device would not turn to the right. Prior to insertion, the device was tested and was able to turn in all directions without difficulty. The physician said that the device would no longer turn to the right as soon as it was inserted into the patient. The insertion was done without difficulty. The physician, staff, and rep present during the procedure do not know what contributed to the device failure. When the device was removed, it appeared to be intact. The patient had no adverse outcome. Another ablation catheter was obtained and the procedure continued without incident. Staff saved the device for reporting purposes and plan to return it to the rep.

Manufacturer response (as per reporter) for bi-directional ablation catheter, Safire TX: The rep was present during the procedure and aware of the problem.

See Warning Letter to St. Jude Medical online available at: http://www.fda.gov/ICECI/EnforcementActions/WarningLetters/ucm162737.htm

Device:

Type: Catheter, Ablation, Cardiac, Hifu
Manufacturer: St Jude Medical, Inc.
Brand: Ultracinch Lp
Model#: UC-LP-11
Lot #: (not provided)

Cat #: 12546
Other #: REF # UC-LP-11

Problem:
The patient was on the table for OHS with planned Maze procedure in progress. The St. Jude Epicor equipment/supplies were being used for the Maze procedure. The device cable connection was never confirmed. Upon troubleshooting it was found that the UltraCinch device, which was on the field and already wrapped around the heart, was not functioning. It was removed and replaced with another similar device which worked. There was no adverse outcome to the patient.

Per Biomed Dept who checked the machine " ...St Jude Ablation Generator functions fine, the problem is the disposables."

Device:

Type: Electrode, Defibrillation/pacing
Manufacturer: Covidien Kendall
Brand: Medi-trace Cadence Pre-connect Rts
Model#: 22770PC
Lot #: 907226 (believed lot#)
Cat #: 22770PC
Other #: (not provided)

Problem:
The nurse opened the outer plastic package of defibrillator/pacing electrodes. She was unable to open the inner package. Scissors were used to open the package. The nurse had to cut around the machine cable that protrudes from the inner package. No patient adverse event resulted. The package is stored in temperature controlled storage rooms maintained at normal room temperature. Biomed took an unopened package and opened it. The same problem was encountered and there was difficulty getting the electrodes out of the package. However, another biomed from another facility attempted to open the package. He intuitively opened the package correctly. He just tore the tab all the way across the package despite the cable protruding through the tab. We believe that this is poorly designed packaging that should be changed and the manufacturer should emphasize proper instructions for opening the packaging.

Manufacturer response (as per reporter) for pacer defibrillation pad (Pre-connect), Medi-Trace Cadence PC:
Manufacturer requested defective product to be returned. Since that product had already been discarded, we area sending sample of what is believed to be the same lot number.

Device:

Type: Kit, Sensor, Cardiac Output
Manufacturer: Edwards Lifesciences, LLC
Brand: Flotrac Sensor With Vamp Adult System
Model#: (not provided)
Lot #: 58690644
Cat #: MHD6AZ
Other #: (not provided)

Problem:
Distal piece of FloTrac was loose, allowing leakage and air inside pressure tubing.

Device 1:

Type: Monitor, Icp
Manufacturer: CODMAN & SHURTLEFF INC
Brand: Icp Express
Model#: 82-6634
Lot #: (not provided)
Cat #: 82-6634
Other #: (not provided)

Device 2:

Type: Monitor, Physiological
Manufacturer: GE Healthcare
Brand: Solar 8000 M
Model#: Solar 8000M
Lot #: (not provided)
Cat #: (not provided)
Other #: (not provided)

Problem:
Patient transferred from ED to NICU. There were some issues noted in tech report called to the NICU as well as in the documentation. Patient came in with an intraventricular hemorrhage and had a ventriculostomy placed. In report to the NICU nurse, the ED staff reported that the patient's ICP was 44. The neuro ICU Intensivist overheard this report and contacted the Neurosurgery resident to re-examine the patient in the ED. When the resident arrived, the patient's ICU was in the teens, as it had been when he initially placed the ventric. The resident reported that when he asked the nurse what the number was being read, the nurse pointed to the Cerebral Perfusion Pressure (CPP) value on the monitor instead of the ICP value.

Device:

Type: Pump, Cardiopulmonary, Centrifugal
Manufacturer: Terumo Medical Corporation
Brand: Sarns
Model#: (not provided)
Lot #: LF04
Cat #: 164275
Other #: Lot # from Tubing pack LF18T

Problem:
Delphin Centrifugal pump (disposable) started squeaking during priming. The pump was changed out without incident prior to initiation of bypass. The patient was not exposed to the squeaky pump head.

Device:

Type: Tubing, Compression Device
Manufacturer: Covidien Kendall
Brand: Scd Express
Model#: (not provided)
Lot #: 811206364 (all same lot)
Cat #: 9528
Other #: (not provided)

Problem:
In the past 3 weeks, we have had 17 occurrences of tubing failure on model 9525 SCD Express Kendall sequential compression devices. All tubing sets are breaking in the same place at the connector of the hosing that then goes into the pump. When this connector breaks off, the patient does not receive therapy. The pump does give a leak alarm when this occurs. The tubing is multiple-use, and cleaned with a germicidal solution. We don't believe the pump is the problem, but suspect a manufacturing defect in the tubing sets, since it is the same port on all of the hoses that has broken.

See device image


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GASTROENTEROLOGY &UROLOGY

Device:

Type: Catheter, Foley
Manufacturer: Coloplast Corporation
Brand: Coloplast
Model#: (not provided)
Lot #: 1547572
Cat #: 408
Other #: (not provided)

Problem:
PICU nurse pulled product off shelf for patient use and discovered hair inside packaging prior to procedure. All products with same lot number were pulled from floor's inventory.

Device:

Type: Crrt, Hemodialysis
Manufacturer: Gambro Renal Products, Inc
Brand: Prisma
Model#: PRISMA
Lot #: (not provided)
Cat #: (not provided)
Other #: (not provided)

Problem:
I came on shift and was in the patient room after getting report. It was noted that blood tinged effluent was in bag on CRRT (continuous renal replacement therapy) machine. The night nurse said it had been like that since starting machine. PTT (partial prothrombin time) result was called from lab. Heparin was stopped and doctor was paged. He called back promptly and we stopped CRRT machine. The clinical nurse manager was notified and clinical engineering came to unit. We left tubing attached to machine with all bags with the bloody effluent. The machine was wrapped in a red biohazard bag and the clinical engineer took the machine away. The lab also called the am CBC which had a significant drop. It was called that blood from chemistry draw after it was spun on machine looked like "tomato soup". Patient was transfused with one unit of PRBC and labs redrawn after transfusion. Doctor was also in unit and ordered work-up for possible DIC/hemolytic anemia. The patient was started on steroids.

Device:

Type: Dialyzer, Hemodialysis
Manufacturer: Fresenius Medical Care North America
Brand: Optiflux F180 Nr
Model#: (not provided)
Lot #: 09CU01018
Cat #: Optiflux F180 NR

Other #: (not provided)

Problem:
Shortly into hemodialysis the technician noticed a small amount of blood leaking on floor from a cracked dialyzer. Arterial end of system re-infused, and the rest of the system was discarded for safety. Approximate blood loss was 150 ml. A new dialyzer and lines were set up. Patient asymptomatic.

Device:

Type: Dialyzer, Hemodialysis
Manufacturer: Fresenius Medical Care North America
Brand: (not provided)
Model#: (not provided)
Lot #: NA
Cat #: F180 NR
Other #: (not provided)

Problem:
Dialyzer was found to have a cracked fiber and was alarming blood leak. System wasted, and blood not reinfused. New system was set up and dialysis restarted. There was approximately 200 ml of blood lost.

Device:

Type: Endoscopy Pump Tubing/cap Set
Manufacturer: Byrne Medical
Brand: Erbeflo
Model#: (not provided)
Lot #: ST2009-070
Cat #: (not provided)
Other #: (not provided)

Problem:
A total of five devices, all from the same lot number, are being reported with this one report. Staff opened a package of tubing to set up the room for an endoscopy. Upon opening the package and before it was used, the RN noticed that the tubing was cracked and separated from the cap. We have seen this problem in the recent past and continue to be in contact with the manufacturer’s representative. Multiple lots have been affected. The product is stored in a cabinet on the endoscopy unit. The product remains in its original box until it is needed for a case. This is the only product stored in that cabinet. The product comes from the manufacturer via the manufacturer's distributor. When it arrives at the hospital, it comes through our receiving dock and then goes directly to Endoscopy. The device is not exposed to temperature extremes (heat or cold) during

shipping, receiving, or storage. This is an ongoing problem that we are experiencing. The rep has been notified each time staff identifies the problem & all product has been returned to the manufacturer.

The rep told the staff that the manufacturer has had several facilities complaining of the same findings-cracked tubing upon opening the packaging. The manufacturer believes that the cracks are related directly to the way that the device is packaged in that the tubing is wound too tightly. It is unknown why the tubing is cracked upon opening the package. Staff is frustrated in that they are opening multiple packages before they can find one that is not cracked. There is no other similar product on the market that the staff can use with our equipment. The uncracked tubing is from the same lots as those that are cracked. There does not appear to be a pattern in the lot numbers for cracked versus uncracked tubing. Endoscopy staff notified the manufacturer and returned the product.

See device images


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Device:

Type: Foley Catheter
Manufacturer: Bard Medical
Brand: Cr Bard, Bardex All-silicone Foley Cather With Ez-lok Sampling Port
Model#: Bardex All-Silicone Foley Catheter with EZ-Lok Sampling Port.
Lot #: unk
Cat #: unk

Problem:
After completely deflating the foley catheter balloon, patients experienced pain and sometimes bleeding upon removal of the foley catheter. After removal from patient, numerous foley catheters displayed a ridge near or on the balloon causing difficulty with removal and pain. This occurred throughout the hospital where foley catheters were removed from patients.

Device:

Type: Hemodialysis Machine
Manufacturer: Gambro Renal Products, Inc
Brand: Phoenix
Model#: (not provided)
Lot #: (not provided)
Cat #: (not provided)
Other #: (not provided)

Problem:
Machine suddenly stopped during a treatment. Machine had a general safe state alarm that attributed to failure of the PI/PO failure of the T1 test. The cause of the failure was traced to a leak present in the PUF peristaltic pump segment failure. Changed the pump segment and T1 test passed four consecutive times.

Device:

Type: Hemodialysis, Crrt
Manufacturer: Gambro Renal Products, Inc.
Brand: Prismaflex
Model#: Prismaflex
Lot #: (not provided)
Cat #: (not provided)
Other #: (not provided)

Problem:
CRRT (continuous renal replacement therapy) machine's screen reacted very slowly to a change to the patient fluid removal rate. Then main screen said memory malfunction. The device would not restart. The 1-800 number on the machine was called and the operator still couldn't get machine to work. CRRT was taken down. Pt's physician and renal fellow decided not to restart CRRT. No injury to patient. Family at bedside and notified.

GENERAL & PLASTIC SURGERY

Device:

Type: Blade, Biopsy Shaver
Manufacturer: Personna American Safety Razor Company
Brand: Dermablade
Model#: 72-0001
Lot #: 1007, 1308, 0908, 0808, 0807
Cat #: 72-0001
Other #: (not provided)

Problem:
When Dermatology was getting ready for a procedure and the nurse opened the package dropping it onto the sterile field, another nurse noted that the blade "looked funny". The sterile blades were covered in brown spots that could be rust or bacteria.

Manufacturer response (as per reporter) for blade, biopsy shaver, Dermablade

They stated that they will conduct an evaluation, but we have not heard back from them. We also sent them photos of the rusted blades.

See device images


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Device:

Type: Breast Biopsy Marker
Manufacturer: Bard Biopsy Systems
Brand: Ultraclip Ii
Model#: (not provided)
Lot #: HUTA1249
Cat #: 861017
Other #: (not provided)

Problem:
MD unable to remove safety on tissue marker. This occurred outside of the breast - item had no contact with the patient. No injury to patient. New tissue marker used without difficulty. Please note that this is the second marker in a week that has had this problem.

Device:

Type: Implantable Mesh
Manufacturer: Covidien
Brand: Parietex Mesh
Model#: (not provided)
Lot #: pgj00517
Cat #: pco2015
Other #: (not provided)

Problem:
The patient had a hernia repair with prolene mesh. The patient had recurrence; the original mesh was removed and a second repair was done using parietex mesh. Approximately one year after the parietex mesh was implanted, the pt reported pain around the area of the hernia repair. She had surgery to remove the tacks that appeared to be causing her pain, but the parietex mesh was left in place.

Approximately one year later, the patient developed another hernia recurrence and returned for surgery. The surgeon noticed a small hole, about a centimeter in diameter, in the center of the mesh with hernia recurrence through this hole. The hernia was reduced and the hole was repaired and another mesh was placed anterior to the abdominal wall to reinforce the repair. The surgeon found no signs of infection around the mesh.

Device:

Type: Robotic Surgical, Camera
Manufacturer: Intuitive Surgical, Inc.
Brand: Da Vinci S
Model#: Model S
Lot #: N/A
Cat #: N/A
Other #: N/A

Problem:
The patient was undergoing a robotic prostatectomy. During the procedure, the 3D camera component of the surgery robot failed resulting in the conversion of the surgery to an open procedure. This was a new da Vinci robot. The vendor determined that the Vision Acquisition Module needed to be replaced. They also stated that Head Sensor Beam on the surgeon console "may be weak."

Device:

Type: Suture, Absorbable
Manufacturer: Ethicon, Inc.

Brand: Coated Vicryl, Control Release
Model#: (not provided)
Lot #: BA2511
Cat #: JJ41
Other #: Needle CT-1 CR/8

Problem:
Multiple scrub technicians and surgeons have noticed the sutures releasing prematurely from the needle on some of the Vicryl CT-1 controlled release sutures. As the suture was being removed from the package with very little force used, the needle would separate from the suture. This did not happen with every suture in the pack, but enough to recognize there was a problem. Surgeons would complain that as they passed the needle through tissue that the needle would come off the suture.

Manufacturer response (as per reporter) for Suture, Absorbable, Coated Vicryl, Control Release:
No response from manufacturer. Vendor representative said that the suture had been sent to their headquarters for testing and evaluation.

Device:

Type: Table, Surgical
Manufacturer: Mizuho OSI
Brand: Mizuho Surgical Table
Model#: Axis Jackson System
Lot #: (not provided)
Cat #: (not provided)
Other #: (not provided)

Problem:
During a procedure a burning smell was noticed. Biomed was called and all equipment was unplugged and sequestered. It was determined that the smell was coming from the surgical table. The patient was examined, no injury was noted.

Manufacturer response (as per reporter) for Surgical table:
Device still under warranty "compressor in the modular unit had burnt up".

Device:

Type: Table, Surgical
Manufacturer: SKYTRON
Brand: Skytron 3600b
Model#: 3600B
Lot #: (not provided)

Cat #: (not provided)
Other #: (not provided)

Problem:
>300lb pt on bed when it loosened from post and fell. Pt in steep trendelenburg. Pt slipped from bed.

Device:

Type: Wound Dressing
Manufacturer: ConvaTec Professional Services
Brand: Aquacell
Model#: (not provided)
Lot #: (not provided)
Cat #: (not provided)
Other #: (not provided)

Problem:
Called to evaluate infant with tracheotomy with progressive respiratory distress, high ventilatory pressures, low tidal volumes and poor breath sounds. Emergent DL/B and removal of plug done at bedside with anesthesiology. Removal of 3-4 pieces of foreign body (appears to be Aquacel absorbable dressing) from above, below and within trach stoma. Sent to pathology and confirmed to be Aquacel. Ventilatory status immediately improved.

GENERAL HOSPITAL

Device:

Type: Catheter, Conduction, Anesthetic
Manufacturer: I-Flow
Brand: On-q Silversoaker
Model#: anti-micro bio soaker catheter 2.5 inch
Lot #: (not provided)
Cat #: (not provided)
Other #: On Q Pain Buster Kit # is PM013-A

Problem:
Dr. was using double catheter OnQ pump. Dr. attempted to flush the catheter after it was inserted into breast implant pocket. It wouldn't flush. He attempted 2 different syringes and no "kink" was noted. This was catheter pulled out, and patient was left without.

Device:

Type: Infusion Pump
Manufacturer: ALARIS Medical Systems, Inc.
Brand: Signature Gold
Model#: (not provided)
Lot #: (not provided)
Cat #: (not provided)
Other #: (not provided)

Problem:
A critically ill, unstable patient on multiple infusions was being transported emergently for a test/procedure. The double chamber infusion pump failed midway during transport. The nurse disconnected a non-critical therapy from another working pump that was safe to infuse via gravity. Then, the working pump was reprogrammed to infuse the critical therapy from the malfunctioning pump until a replacement pump could be obtained. This is the second time this happened in one day on two different pumps.

Our biomedical engineering department found that the Alaris infusion pump suffered two "Entire Instrument Illegal Resets." According to the Alaris Tech support, these errors are microprocessor errors and the instrument is in need of repair. The pump(s) were sent to the manufacturer for further analysis and repair.

Device:

Type: Infusion Pump
Manufacturer: Baxter Healthcare Corporation
Brand: Colleague 3cx
Model#: (not provided)
Lot #: (not provided)
Cat #: (not provided)
Other #: (not provided)

Problem:
The triple channel Colleague CX infusion pump was sent to the biomedical engineering department because the nurse noticed the guardian/drug library settings were altered from the standard set that they utilize. Our in house biomedical engineering department confirmed the guardian/drug library settings had “defaulted” back to the factory settings, and our customized settings that are specific to our hospital were lost (standard drug concentration settings, dosage limits/warnings, etc). The pump did not notify the user of this alteration in the guardian/drug library settings. There are serious patient safety implications associated with this failure including inadvertent over or under-infusion, unintended boluses, etc. This has occurred 2-3 other times in the past with the Colleague CX pumps.

During testing of the pump by our in house biomedical engineer, it was noted in the

device history log that one week prior to the pump coming down for the guardian/drug library issue, the pump was reset due to a depleted battery alarm. The next day (day after the depleted battery alarm), there was an 812.02 failure code noted on Channel A of the device, which had rendered Channel A inoperable. The nurses continued to use Channel B and Channel C.

Device:

Type: Infusion Pump
Manufacturer: Hospira Global Medical Affairs
Brand: Symbiq
Model#: (not provided)
Lot #: (not provided)
Cat #: (not provided)
Other #: (not provided)

Problem:
When assessing hourly vitals, the pump was noted to have a white screen with error message 15 displayed and was not infusing. We are unsure of how long the medication had not been infusing. There was no alarm generated to notify the clinician of the error. This was concerning because patient had just had a stent inserted and was on a medication to keep the stent patent at time the pump was found to be nonfunctional. Our biomedical engineering department verified S308 errors in the log file. We returned the pump to the manufacturer for repair.

Device:

Type: Infusion Tubing
Manufacturer: ALARIS Medical Systems, Inc.
Brand: Smartsite Needle-free Valve Infusion Set
Model#: 2420-0007
Lot #: (not provided)
Cat #: 2420-0007
Other #: (not provided)

Problem:
The nurse was weaning the patient off of one vasopressor while increasing a different vasopressor. However, the patient's blood pressure was still low. The nurse looked at the fluid chamber on the infusion tubing and noticed that no medication was being pulled from IV bag. All infusion lines were checked, and the IV tubing was switched to a different pump module, and it was still not dripping appropriately from the bag. Once the tubing was changed, the patient's blood pressure increased appropriately.

Device 1:

Type: Infusion Tubing
Manufacturer: Hospira Global Medical Affairs
Brand: Lifeshield Microclave Connection System/ Microbore Extension Set
Model#: 12549
Lot #: (not provided)
Cat #: 12549
Other #: (not provided)

Device 2:

Type: Needle Free Closed Iv Connection System
Manufacturer: ICU Medical Inc.
Brand: Microclave
Model#: (not provided)
Lot #: (not provided)
Cat #: (not provided)
Other #: (not provided)

Problem:
During IV and PICC line dressing and maintenance, as the clinician removes a male connection from the microclave connector, the spring loaded return mechanism sticks and does not seal the clave connection. This failure results in fluid leaking from the clave port which compromises sterility. We initially discovered this when we noted an increase in blood stream infections, and found this defect as part of our investigation. This failure is noted to occur after clave has been in position for up to three days. Our staff has been unable to provide lot numbers as packaging is discarded during initial use. One unit has had more than 12 failures of this type. The manufacturer has replaced the complete inventory. However, our clinicians have determined that the new product has exhibited the same sticking issue as the old inventory.

See device image


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Device:

Type: Oral Swab
Manufacturer: Sage Products Inc.
Brand: Toothette
Model#: 5602
Lot #: (not provided)
Cat #: (not provided)
Other #: (not provided)

Problem:
While doing oral care, the sponge came off the toothette in the patient's mouth. It traveled down into the pt's throat. The Nurse Practitioner used a glidascope and Magill forceps to retrieve the sponge.

Device:

Type: Pump, Infusion, Implanted, Programmable
Manufacturer: Medtronic Neuromodulation
Brand: Synchromed 2
Model#: (not provided)
Lot #: (not provided)
Cat #: (not provided)
Other #: (not provided)

Problem:
Pt was wheelchair bound with spasticity. Pt receiving Baclofen via medtronic implanted pump that was placed ~1yr, 5 mo prior. The pump alarmed. Pt called Medtronic and told them it was a "critical alarm". Pt went to ED and was admitted. Pt had surgery for replacement of pump.

Recall at manufacturer's website online available: http://www.medtronic.com/your-health/chronic-back-and-leg-pain/important-safety-information/product-advisories/index.htm

Device:

Type: Syringe Pump
Manufacturer: Smiths Medical MD, Inc.
Brand: Medfusion
Model#: 3010A
Lot #: (not provided)
Cat #: (not provided)
Other #: (not provided)

Problem:

A Medfusion syringe pump was infusing a norepinephrine drip to a patient. During the norepinephrine drip change, a new drip was hung to run on the indicated pump. The nurse came back ten minutes later to scan for the electronic medical administration record and the pump was found to have a blank screen. The display was illuminated, but there was nothing present on the screen/display. The nurse pushed the green start button, but nothing happened. The syringe was removed from the pump and moved to a new syringe pump. The patient had significant drop in blood pressure requiring a fluid bolus. While switching the drip to a new syringe pump, the patient received an unintended bolus of norepinephrine and had a significant high blood pressure. After the patient was stabilized, the nurse returned to evaluate the malfunctioning syringe pump.

An empty 60 mL syringe was placed in the syringe pump to use for evaluation. After accessing the main screen, the alarm displayed: "System failure: Positive supply bgnd test" appeared as a banner across the top of the display. The pump would not start and was sent to the risk and Clinical Engineer departments. The Clinical Engineering tech evaluated pump and was able to reproduce the problem when loading the syringe, the screen went blank and system failure alarm sounded. This was the same failure the nurse was having. When the plunger position moved, the display would come and go. The tech verified it had the same system failure alarm as before, "System failure: Positive supply bgnd test" message displayed.

The manufacturer was notified, and they indicated a bad power supply output would cause this error to be displayed. The pump has been sent to the manufacturer per their request to further evaluate the failure.

Device:

Type: Thermometer, Typanic
Manufacturer: Covidien
Brand: Genius 2
Model#: Genius 2
Lot #: (not provided)
Cat #: (not provided)
Other #: (not provided)

Problem:
Many thermometers are returned to Biomed because of a defective scan button which are then returned to the manufacturer for repair.

Additional information obtained from the site:
All other defective thermometers have the same model number, Genius 2.
No patient's harm. This would have only caused a delay in recording the patients temperature and other vital signs.

Device:

Type: Urine Collection Kit
Manufacturer: Becton Dickinson
Brand: (not provided)
Model#: REF # 364956
Lot #: (not provided)
Cat #: 8010719
Other #: (not provided)

Problem:
A patient presented to the outpatient lab to give a clean-catch urine specimen. The staff provided the patient with a collection kit, which includes a packaged castile soap towlette. The patient returned to the desk shortly afterwards and gave the unused towlette to the staff. The patient discovered dark green colored areas along one edge of the folded towlette and reported that it looked like mold. The staff opened up another kit and experienced similar findings. In both cases, the kits were from the same lot/reference numbers and were completely sealed as were the towlette packages. There was no evidence of condensation inside the kits. The kits are stored in a humidity and temperature controlled area inside the department. Staff opened a third kit and towlette, which showed no similar mold appearing markings. The patient was provided a new kit with which to obtain a specimen. Staff are concerned that had the patient not brought this to their attention the results of the urine culture and sensitivity could have been affected if the substance was mold. It may have altered the medical treatment plan. Staff have not seen this in the past and have found no other instances of a mold like substance in the packaged towelettes. One towelette was saved, which we will return to the manufacturer if they would like to inspect/analyze it.

MICROBIOLOGY

Device:

Type: Culture &Transport System
Manufacturer: Becton Dickinson
Brand: Bbl Culture Swab
Model#: (not provided)
Lot #: (not provided)
Cat #: 22009
Other #: (not provided)

Problem:
Surgeon was using Q-tip to culture wound through an arthroscopy incision. After insertion into incision, surgeon used twilling motion on Q-tip handle. As the surgeon was attempting to remove the Q-tip, about an inch of tip broke off into incision. Surgeon looked for the Q-Tip and had to make a small incision to debride the tissue and remove the Q-tip.

Device:

Type: Sterile Mucus Specimen Traps
Manufacturer: Busse Hospital Disposables
Brand: (not provided)
Model#: (not provided)
Lot #: 0821027
Cat #: 406
Other #: (not provided)

Problem:
The laboratory has received many of these containers that were not leaking from the screw containers but rather from the tubing section. In some cases, irretrievable specimens have been lost in transport as a result of the leakage. The laboratory has attempted a number of methods to better seal these containers in order to prevent specimen loss, but with have had minimal success.

ORTHOPEDIC

Device:

Type: Arthroscope, Shaver
Manufacturer: Ascent
Brand: Blade
Model#: (not provided)
Lot #: 210573
Cat #: 7205305
Other #: 3.5mm Full Radius

Problem:
Device clogged and would not function

Manufacturer response (as per reporter) for 3.5mm Full Radius Shaver, Arthroscopic Blade: Rep notified by OR Materials person

Device:

Type: Drill, Orthopedic
Manufacturer: Zimmer
Brand: Gold
Model#: (not provided)
Lot #: (not provided)

Cat #: (not provided)
Other #: (not provided)

Problem:
Surgeon drilled for inferior locking screw. Drill bit broke, leaving approximately 1" of bit in place. Surgeon decided would be best to leave in place. Surgery completed and wound closed. Patient discharged from hospital. Readmitted two weeks later for shoulder infection. Antibiotics given; incision and drainage done on 3 days after readmission. Patient discharged 4 days after readmission.

PHYSICAL MEDICINE

Device:

Type: Specialty beds
Manufacturer: Kinetic Concepts, Inc.
Brand: KCI air bed
Model#: 40030A; 837
Lot #: (not provided)
Cat #: (not provided)
Other #: (not provided)

Problem:
RN walking past door, found pt with knees on floor and upper body/head wedged between siderail and bed. Patient on air mattress with Posey Vest on. RN yelled to Tech for help, RN tried to hold patient up to keep from further slipping and strangling pt on siderail. Tech and other RN entered room, RN's holding patient up, patient kept slipping, more RNs entered room. RN yanked side rail out while other 2 RN's freed pt from siderail and helped lower the rest of the way to the floor. By this time room was full on RNs and MD was at bed-side to assess. Vitals were taken while patient was laid on floor and lift team was called. Bed was changed from air mattress to regular bed r/t regular bed a lot less slippery for patient. Patient was agitated and stated he had to go to the floor and wanted to get out of the hospital.

See device images


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Device:

Type: Bed, Patient Rotation, Powered
Manufacturer: Kinetic Concepts, Inc. (KCI)
Brand: Rotoprone
Model#: 60040
Lot #: (not provided)
Cat #: (not provided)
Other #: part#: 209500

Problem:
Malfunction code appeared on screen of RotoProne bed. Instructed user to unplug and then plug the power cord back into outlet. After that was done, the screen instructed user to return patient back to 0° supine, engage lock pin to clear the message, and if the error message remained to call manufacturer. Manufacturer was contacted due to the fact that the patient was too unstable to tolerate a supine position. The plan was to leave the patient prone until technicians arrived to troubleshoot the bed. The clinical team contacted the 24-hr hotline and operator notified team member that a technician will contact the hospital department with their action plan. A clinical representative and technician arrived two hours later to troubleshoot the bed and assist in safe transfer. A replacement bed request was made to address the malfunction. After the patient was

rotated supine per manufacturer's instruction, multiple error messages appeared and the patient began rapid O2 desaturation. The emergency lever of the bed was engaged to initiate rotation back to prone. With the bed/patient in mid-rotation the technicians stated they can no longer rotate back into prone position once the emergency lever was engaged. A phone call was placed to check the status of the replacement bed. It was later discovered that the bed was just outside of our area and in its last 20 minutes of its quality control checks.

RADIOLOGY

Device:

Type: Computed Radiography Reader And Workstation
Manufacturer: AGFA Healthcare Corp.
Brand: Agfa Cr Reader /Qs Work Station
Model#: PRECISION 670 QS SVR
Lot #: (not provided)
Cat #: (not provided)
Other #: (not provided)

Problem:
Patient was re-exposed after AGFA equipment failed to send images from digital reader to workstation. After 30+ minutes the images were transmitted. At that time the pt had already been X-rayed a second time.

The device was so slow that staff believed it to be defective and ordered another X-ray exposure. The device continued to cause problems and failed to retrieve other images, causing delays in care and exposing other pt's to double exposures.

AGFA responded and repaired the CR Reader. The problem arose from certain patient medical alert info. The data held within the "medical alerts" field of the patient record was found to cause problems when it was greater than 64 characters. This feature has been disabled and the CR Readers continue to work normally.

Device:

Type: Computed Radiography Reader And Workstation
Manufacturer: FujiFilm Medical System USA, Inc.
Brand: Iip
Model#: IIP
Lot #: (not provided)
Cat #: (not provided)
Other #: 1174572

Problem:
Delay in treatment related to equipment failure on 4 patients. The images were frozen on the list and would not transmit on the Fuji Reader equipment. The system was rebooted without change. A few hours later the system was again shut down and rebooted and the images then did transfer. Images were repeated on equipment in another department. The next day the same issue occurred with 4 more patients and the system was shut down to await evaluation by the manufacturer.

This problem was traced to a computer virus (Conficker) which was found to be affecting 6 Fuji CR units. The hospital's Imaging service engineer applied a Microsoft patch (MS08-067) to the 6 Fuji units to prevent the virus from re-infecting the systems.

Subsequent to this problem one of the Fuji units experienced a shutdown, which was repaired by replacement of a defective power supply. This failure is not thought to be related to the virus issue.

Device:

Type: Lead Shield, Ceiling Mounted
Manufacturer: Ti-Ba Enterprises
Brand: Mavig
Model#: 1624520
Lot #: (not provided)
Cat #: (not provided)
Other #: (not provided)

Problem:
During patient prep for a Cath Lab procedure a staff member was moving the Doctor's lead shield away from the patient when the support arm broke off from the vertical connector on the ceiling. One end hit a staff member just above the eye, the other end landed on the RN's lead shield, missing the nurse. The patient was not hit and was unaffected. The support arm was manufactured by Mavig but was sold as part of the Imaging system. On inspection, it appeared that there was a stress fracture in the mount.

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Medical Device Problem Summaries

Summary of MedSun Reports Describing Adverse Events With External Defibrillators

Print Item
E–mail Item

An external defibrillator is a device which can analyze a person's heart rhythm and subsequently determine whether or not a shock is required to maintain normal heart rhythm. External defibrillators will often use voice prompts, light, and text to advise the rescuer through the proper life saving steps.1

Over the past 2 years, MedSun has received 64 adverse event reports associated with external defibrillator devices manufactured by Medtronic Inc., Philips Medical Systems Inc., Physio Control Inc., and Zoll Medical Corp. The reports were submitted by 30 hospitals between July 2007 and July 2009.

The reported device problems are categorized below:
• Device fails to deliver shock
o Error message displayed (4)
o Simple failure of device to deliver (4)
o Faulty cable (2)
o Device Shuts off (1)
o Device Memory Full (1)
• Low Energy/200 J insufficient, 360 J needed(9)
• User Error (7)
• Pacer malfunction (6)
• Power board defect (5)
• Shock ineffective (3)
• Handle breaks off (2)
• Paddles malfunction (2)
• Pads cause burn (2)
• Screen Blank (1)
• Failed test (1)
• Sparks cause fire/burn (1)
• Battery Issue
o Will not turn off/on (7)
o Will not charge/needs AC or DC (3)
o Battery not secure; resulting power loss (1)
o Ran out of battery (1)
o Over Charged; leaked (1)

A total of 7 reports involved a patient death.
• Death as a result of no shock being delivered (6)
• Death as a result of device shutting off (1)

A total of 6 reports involved a patient/staff injury.
• Delayed defibrillation resulting from no shock delivered (1)
• Patient burned by pads and/or spark (3)
• Healthcare provider hit by falling defibrillator when handle broke (2)

Of the reports that listed patient age, 1 patient was less than 21 years and 34 had a patient age listed as greater than 21 years. Of the reports that listed patient gender, a total of 13

reports involved female patients and a total of 23 reports involved male patients.

These MedSun reports contributed to FDA awareness of the device problems. The following recalls, describing various problems, are noted to be associated with the external defibrillator devices. Reported events involving specific external defibrillator devices may, or may not, be involved in the recall(s) listed.

Adverse Event Table

Recall Number	Product	Recall Class	Date	Recalling Manufacturer	Reason for Recall
Z-1656-2009	AED 10 and MRL Jumpstart	2	7/6/2009	Welch Allyn Protocol Inc	Possible for users to misunderstand signals. The original product labeling told users that a flashing low battery indicator signals that the battery is low and requires changing soon. If a user experiences a flashing low battery status indicator and does not understand that the device can continue to be used the user might choose not to continue operating the device.
Z-1390-2009	HeartStart MRx Defibrillator/Monitor	2	6/2/2009	Philips Healthcare Inc.	Spontaneous turn-on which could deplete the battery rendering the device unusable until power is restored. There is also the possibility of a failure mode in which the device fails to respond to

					user initiated turn-on rendering it unusable for monitoring and therapy.
Z-1007-2009	AED 10	1	3/10/2009	Welch Allyn Protocol Inc	Potential for device to deliver less than the programmed energy.
Z-1005-2009	Welch Allyn AED	1	3/10/2009	Welch Allyn Protocol Inc	Potential for device to shut down prematurely under certain circumstances.
Z-1006-2009	AED 10	1	3/9/2009	Welch Allyn Protocol Inc	Reliability issues - potential to shock a non shockable rhythm or not shocking a shockable rhythm;
Z-0919-2009	Powerheart G3	2	2/25/2009	Cardiac Science Corporation	Potential for AED to not deliver defibrillation therapy.
Z-0149-2009	LIFEPAK CR Plus	2	10/30/2008	Physio Control Inc.	The device may not power on although it indicates it is ready for use and would not be able to provide defibrillation therapy.
Z-2337-2008	Philips HeartStarMRtX	2	9/25/2008	Philips Medical Systems	Defective internal memory cards may exhibit one or more of the following behaviors: Device repeatedly restarts approximately every 20 seconds or Slow device start-up of approximately 15

					seconds or more. During this time the MRx displays either a blank screen or the Philips HeartStart MRx Start-up screen prior to displaying the selected mode of operation (i.e. Monitor AED Pacing or Manual Defib
Z-2388-2008	Lifepak Defribrillator/Monitor	2	9/21/2008	Physio Control Inc.	Potential for the coin battery to drain prematurely causing the monitor clock time and date to be incorrect and the service light indicator to illuminate.
Z-2035-2008	Internal handles and electrodes for LIFEPAK 9 LIFEPAK 9P LIFEPAK 12 AND LIFEPAK 20 Defibrillator/	2	9/16/2008	Physio Control Inc.	Based on testing sterilization methods described in labeling may be ineffective and may cause damage or corrosion to the paddles or handles. If handles and/or paddles are not sterilized adequately and are used on a patient there is a risk of infection. If handle discharge button is damaged during sterilization defibrillation therapy may be prevented.

Z-1656-2008	LIFEPAK 1000	2	9/16/2008	Physio Control Inc.	Potential for the display screen to dim and eventually go blank. The risk to patient is a delay in defibrillation therapy if the defibrillator was needed in a cardiac arrest situation. Death or permanent impairment can occur if the user fails to deliver a defibrillation shock or defibrillation is delayed.
Z-1904-2008	LIFEPAK 12 defibrillator/monitor	2	9/16/2008	Physio Control Inc.	The LIFEPAK 12 defibrillator / monitors with software version 130 have an increase in likelihood for an incorrect Shock Advisory Algorithm (SAS) decision if the Auto Analyze setting in AED mode is On leading to incorrectly render of shock or no shock decision. When Auto Analyze is set to On in AED mode the device initiates the SAS analysis immediately (no waiting period or warning prior to analysis
Z-2341-	LIFEPAK CR Plus	1	9/16/2008	Physio Control	This recall is being

2008				Inc.	conducted due to the device being configured with the incorrect software for semi-automatic instead of fully automatic use. When the device is needed for a cardiac arrest emergency the device will require that the user press the shock button instead of automatically delivering a shock as per the normal operation of the fully automatic device. Fully automatic defibrillators h
Z-1858-2008	Physio-Control LIFEPAK 12 defibrillator/monitor	2	9/11/2008	Physio Control Inc.	The LIFEPAK12 defibrillator/monitor series (LP12) contain a Biphasic PCBA that may have a solder defect on the H Bridge component that could prevent the device from providing a defibrillation shock.
Z-2011-2008	LIFEPAK20 and LIFEPAK20e Defibrillator	2	9/8/2008	Physio Control Inc.	A thicker keypad that may prevent the door from fully latching closed. If the door is not fully closed there is a potential that the defibrillator will not automatically

					change from automatic external defibrillation (AED) mode to manual mode by pressing the MANUAL button located on the lower left corner of the door. This may lead to a delay in defibrillation therapy.
Z-1567-2008	FASTPAK	2	8/24/2008	Physio Control Inc.	Batteries mislabeled - batteries labeled as 2.4 amp/hour batteries however are 1.0 amp/hour batteries.
Z-1779-2008	HeartStart defibrillator	2	7/9/2008	Philips Medical Systems	Buttons Sticking - The On/Off and Shock buttons on the front panel of the device may stick in place when pressed and fail to respond to the button press causing a delay in the delivery of a defibrillation shock when the system advises a shock.
Z-1167-2008	Zoll E Series Defibrillator with 12 Lead ECG	2	6/28/2008	ZOLL Medical Corporation World Wide Headquarters	Incorrect Patient Records: Patient records that have been stored then later transmitted or printed may not be the correct record. Records that are transmitted or printed immediately

					following acquisition are correct.
Z-1616-2008	9051 Electrode Adapter	3	5/21/2008	Cardiac Science Corporation	Adaptor Cable Incorrectly Manufactured: The red and white connector ends of the adapter are switched. Therefore the cable will not connect to the electrodes as indicated in the instructions.
Z-1050-2008	LIFEPAK 20	2	3/29/2008	Physio Control Inc.	Inoperable Device - Potential for delay in therapy or prevention of defibrillation therapy due to corrosion of the Printed Circuit Board Assemblies (PCBA).
Z-0048-2008	Guidant VITALITY AVT ICD	2	11/24/2007	Boston Scientific CRM Corp	Erroneous Display/Atypical Charge Time Behavior: 1)-End of Life (EOL) or ERI is displayed during mid-life (typically 24-48 months) even though battery capacity remains available. 2)-Extended ERI charge time limits: Charge times during mid-life may remain below a normal extension of the ERI charge time . ******

					Prophylactic replacement of these devices prior to ERI is not recommended. As stated
Z-0129-2008	Welch Allyn AED10	1	11/6/2007	Welch Allyn Protocol Inc	Failure to Deliver Shock; a defective capacitor may cause the delay or non-delivery of the defibrillating shock which may result in failure to resuscitate the patient
Z-0062-2008	HeartStart XL	2	10/25/2007	Philips Medical Systems	Inadequate shipping package causing damage to control boards resulting in unit failure. Failure to deliver therapy (defibrillation pacing or cardioversion) may occur as a result of undetected damage to the PCB assembly.
Z-1223-2007	Welch Allyn AED 20 Defibrillator	1	9/19/2007	Welch Allyn Protocol Inc	Failure to deliver therapy: The Welch Allyn AED20 Defibrillators may display a Defib Comm error message on the device display during use which may result in failure of the device to analyze the patient's ECG and deliver the

					appropriate therapy.
Z-1128-2007	HeartStart XL	2	8/7/2007	Philips Medical Systems	The ECG signal may become unusable to assess patient condition and need for therapy.
Z-1148-2007	LIFEPAK 500	2	8/4/2007	Medtronic Emergency Response Systems Inc.	Reduced Shock-the device may deliver 100 Joule (J) to a patient which is less than the recommended factory minimum default setting of 200 J.
Z-0887-2007	Batteries used with the LIFEPAK 20 defibrillator/monitor	2	7/4/2007	Medtronic Emergency Response Systems Inc.	Defibrillator internal battery cell may contain a short which could reduce battery capacity and cause the device to shut down without warning while operating on backup (DC) battery power.

The following tables describe the adverse event reports received relating to external defibrillators.

[Note: The reports have been edited for clarity]

Adverse Event Table		
Device	**Device Identifier**	**Event Description**
Medtronic Inc.,	Device model	On some of the Lifepak 12's, when you push the sync

Medtronic Emergency Response Systems; External Defibrillator	#:LP12	button it doesn't come on and give a triangle on the R wave so you have to charge the joules you want and press the sync button then as usual holding the shock button. After the shock, the sync button is supposed to auto turn off, but it does not. Therefore, if the pt goes into ventricular fibrillation, you have to manually turn off the sync and then defibrillate the patient. This has happened in 3 different units with multiple experienced staff members using the Lifepak 12. Manufacturer response (as per reporter) for Defibrillator, LifePak 12 Our Clinical Eng. dept. contacted the manufacturer then they completed testing on the monitors and they came to conclusion that it was operator error.
ZOLL Medical Corporation; External Defibrillator	Unknown	The staff noted that after being turned off for a couple of minutes, the M Series monitor will not turn on. When the battery was removed and replaced, the device will turn on, but the device will have retained the setting from the previous patient. Multiple batteries were switched out with the same result. The device was then pulled from service. Biomedical Engineering's Corrective Action: The device will not power on using battery alone. The AC power will turn the device on. When the battery is inserted it will not beep four times but it will beep with AC. Software was updated to 39.01. Found broken ZIF connector and disconnected ribbon cable. The device was tested after reconnecting the cable. Same condition noted--device will not power on with battery, but will power on with AC. The system board was replaced (missing front case assembly guide post). The system board replacement solved the reported problem condition. All functions were tested and device works fine. Device returned to service.
Medtronic Inc., Medtronic Emergency Response Systems; External Defibrillator	Device model #:LifePak 12	The patient was in full arrest and CPR was in progress. The patient was shocked (defibrillated) X 2. The staff charged the machine to 200J, but the defibrillator failed to deliver the shock. This was attempted X 3. The red service light appeared as well as error code D00D. The staff turned the machine off, then back on, recharged it and was able to deliver shock. The patient continued in full arrest with asystole and was pronounced 9 minutes later.
Medtronic Inc., Medtronic	Unknown	The patient arrived in the ED in full cardiac/respiratory arrest. She was shocked X 2 with

Emergency Response Systems; External Defibrillator		the Life Pak 12. The defibrillator was charged up to 360J for the third attempt and the red service light appeared along with error code D00D. The machine would not deliver the shock. The nurse turned the defibrillator off and reset the machine. The defibrillator was functional after it was reset but the code was called at this time. The service manual describes code D00D as an SC_ERROR_SCI_MSGQ_ERROR. Manufacturer Response: Field rep e-mail says trying to get more official letter that explains problem and ok's device for use. States "the LP-12 had a memory buffer software glitch that inhibited the shocking of the defib and prompted a service light and lock up. The D00D error code is a very rare event" He checked with the MDR and engineering folks, did a complete Performance Inspection Procedure on the machine, cleared the error codes and installed the latest -134 software. He then states "It has the OK from us to be put back into service"
ZOLL Medical Corporation; External Defibrillator	Device model #:CCT	A staff member was retrieving a Zoll CCT defibrillator to use for a transport when the handle snapped away from the defibrillator. This caused the defibrillator to fall and strike the caregiver in the upper leg. The handle broke on both pivot hinges completely separating from the defibrillator. The staff member complained of pain and bruising but did not want to pursue medical intervention. The defibrillator was removed from service for Biomedical evaluation and analysis. This is the third incident of these carrying handles breaking away from this model of defibrillator and the second MedSun report from this facility. The weight of the defibrillator with the battery is approximately 16 pounds. Manufacturer response (as per reporter) for Defibrillator Monitor, Critical Care, Zoll CCT Manufacturer requesting that handle assembly be sent back to them for analysis. A replacement handle was sent from Zoll.
Philips Medical Systems; External Defibrillator	Device model #:M5066A	Clinical engineering was doing a routine check of AED after it had been used in a code across the street from the hospital. The AED functioned properly during the code. The AED is normally stored in the hospital lobby. When clinical engineering was holding the AED, in or out of the carrying case, the unit resets power intermittently and begins self test. Upon further

		investigation it was found that the battery movement caused this and after replacing the battery with a new one the problem no longer occurred. It was determined the battery clip was compacted and once it was bent back into shape, the battery functioned properly.
Medtronic Emergency Response Systems; External Defibrillator	Device model #:LP-20	During surgical procedure, a synchronized cardioversion attempt was made with the device in manual mode. Upon pressing the sync button and observing proper operation, the defibrillator was charged to 360J. After a shorter than expected time, the unit appeared to be ready for discharge. Upon discharge, the unit gave either a "connect electrodes" or a "remove test plug" message. We are not sure which. The unit gave a service light and continued to give the message. Another defibrillator had to be obtained to provide therapy needed by the patient. Pads checked and compatible with defib. ========== Manufacturer response for Defibrillator, Lifepak 20 ========== With Risk Mgmt. approval, call was placed for field service support since the unit is under warranty. The unit gave a 9021 error code at the time of the failure. Their service documentation indicates that newest software should be installed as the corrective action for this. Service rep installed latest software Installed Material: Qty = 1 3203332-019 KIT-UPGRADE,SW,MODULE 070,LP20,ENGLISH Upon further consideration, the rep took the unit with him to deliver to Regulatory Affairs with the company. He updated software on all other units in our OR areas. I am currently trying to make contact with the representative in Regulatory Affairs to try to get this software installed on the rest of our units. We have 79 of them within our facilities.
Medtronic Emergency Response Systems; External Defibrillator	Device catalog #:11131-000001	Post cardiac surgical patient required a thoracotomy for cardiac tamponade and defibrillation. First attempt at defibrillation with internal paddles was unsuccessful when the defibrillator would not discharge. The paddles were connected to a second defibrillator which also would not discharge, before a set of external defibrillator pads were attached and the patient was successfully defibrillated. The lack of timely defibrillation was a result of the failure of the internal paddles cable, which was found to have bent pins in defibrillator connector.

Philips Medical Systems; External Defibrillator	Device model #:M3535A	Upon admission to the ED, external pacing began at a rate of 50BPM with MA of starting at 45 and gradually increased to 80 for a diagnosis of A-fib with slow ventricular response at approximately 30BPM. The patient was moved to the ICU approximately 9 hours later. The next morning, 16 hours after admission, the MA was increased to 110. The patient was taken to the OR 22 hours after admission at which time the defibrillator pads were removed and 4 small, 2cm burns under the left flank pad area. Once removed in the OR, the pads were unfortunately discarded. Photos were taken and there were two small first degree burns. Wound #1: .75cm x 1cm x 0cm: skin intact, no exudate, dark red/purple, surrounding skin normal Wound #2: 1.5cm x 1.25cm x 0cm: skin intact, no exudate, dark red/purple, surrounding skin normal In speaking with our defibrillator rep, he indicated that burns on the skin can occur if the pads are not applied properly. The risk is increased if there are air pockets under the pads. Unfortunately, it is not known exactly how the pads were applied in this case. Biomed examined the defibrillator in question; the paddles, leads and accessories (except the pads). Delivered charge were checked on the defibrillator. All components were checked and passed. The outputs were measured at 20,50,100,150 and 200 joules and all were well within the manufacturer's tolerance level of output. Philips was notified.
Zoll Medical Corporation; External Defibrillator	Unknown	Patient was being treated for atrial flutter during an ablation procedure in the Stereotaxis room. The Stereotaxis system was not being used and was in the stowed position. The patient went into atrial fib and required cardioversion. A Zoll biphasic defibrillator was moved closer to the patient, which put it within 6 feet of the stowed Stereotaxis magnet. The defibrillator was displaying an ECG and "sync markers", showing that it was ready to cardiovert. When the charge button was pressed, it displayed an error code and a “sync error” message. The electrodes were then connected to the second defibrillator (Zoll monophasic) and the charge button was pressed. Again an error message was displayed, reading “defib error”. A third Zoll defibrillator from another area was brought in and, this time, was held in a different location, closer to the patient, by a cath lab staff member. This defibrillator charged and fired normally.

		Patient was cardioverted. The two defibrillators were tested outside of the room and functioned properly. It is believed that the two defibrillators which were originally used may have been located within the "5 gauss line" of the Stereotaxis magnets (about 6 feet). The location of the defibrillator which later charged and fired properly was further from the magnet (next to the patient, at mid-table).
ZOLL Medical Corporation; External Defibrillator	Unknown	During a code, the patient was defibrillated 3 times successfully. On the 4th attempt, the defibrillator would not charge and when the defibrillator button was pressed-no shock was delivered. The message on the monitor was "defib not charged". Another Zoll was attached and the patient was successfully shocked.
Medtronic Emergency Response Systems; External Defibrillator	Unknown	Patient was cardioverted in ICU. The machine delivered the set energy (100 J) and there was a pause after the shock. Then the rhythm was lost via the paddles and we were unable to monitor the patient via the paddles. We did finally manage to get a rhythm via the leads. Patient converted to sinus rhythm. Biomed came up immediately following and did discover that the cable was faulty. The cable was removed and a new cable was attached. The cable was taken by Biomed for further evaluation. They were able to duplicate error. Cable possibly part of a recall.
ZOLL Medical Corporation; External Defibrillator	Device model #:CCT	While carrying a Zoll CCT defibrillator to a patient room for transport, the folding upper handle of the defibrillator snapped and broke away from the device. The defibrillator fell to the floor striking the caregiver in the foot causing injury. Additional Biomedical inspection found an additional Defibrillator with a small crack in the handle which could eventually break. That device was removed from service as well. Manufacturer to investigate and propose solution.
ZOLL Medical Corporation; External Defibrillator	Device model #:M Series	Code Blue was called on the patient. The physician was at bedside. The patient was attached to Zoll pads and connected to a Zoll monitor. The monitor reported "poor pad contact". Zoll pads were rechecked and then replaced. The defibrillator machine was replaced which worked normally. CPR was not interrupted for more than one minute during checks on the pads and machine. Pt expired.
Physio-Control, Inc.; External	Device model #: LP12	Defibrillator failed to fire. Device said service when nurse pushed "shock" Device was fully charged to 360

Defibrillator		joules. Nurse turned device off and recharged to 360 joules and defibrillator than delivered. Patient was in ventricular fibrillation. Defib was turned off and back on which remedied the problem. Fortunately the patient did not have an adverse outcome. This incident is very similar to one that happened roughly 2 years ago where the defibrillator filled up it's memory and would not deliver a shock. At that time it was decided that all of our defibrillator settings would be changed to not record vitals and therefore not fill up the memory thereby eliminating this possible malfunction. With the move to the new LifePak 12s which were purchased, These new defibs did not get the settings changed to not record vitals. Currently Biomed is still in direct contact with the Manufacturer, and waiting for further information, in regards to the meaning of some error logs, and the “Continuous ECG Recording”.
Zoll Medical Corporation; External Defibrillator	Device model #:MSeries	Patient needed to be shocked out of fibrillation. Paddles were placed on patient's chest. No other part of nurse's body was touching bed or patient. Nurse felt shock in left hand and sensation up left arm. Was light headed for few seconds only. Staff injury only.
Zoll Medical Corporation; External Defibrillator	Device serial #:T04J64289	Patient was being defibrillated without difficulty. Then the monitor started to read "low battery" several times even though the monitor was plugged into a wall outlet. The defibrillator would not charge even though it had previously charged and delivered two shocks to the patient.
Medtronic Inc. (Medtronic Emergency Response Systems) ; External Defibrillator	Device model #:LIFEPAK 20; Device lot #: 2003	Defibrillator failed to charge on battery power. When plugged into the wall, the unit worked properly.
Zoll Medical Corporation; External Defibrillator	Unknown	Connected patient to defibrillator and it would not deliver shock. MD requested manual paddles and new defibrillator which was provided and shock delivered. Biomed called and checked initial defibrillator with no problem found. After review of event, it was noted that start up mode of defibrillator was on leads instead of pads. Physician repositioned pads prior to mode change in preparation to reopen chest. Repositioned pads were not adhering to chest wall.

Zoll Medical Corporation; External Defibrillator	Device model #: M series	Attempted cardioversion on a patient whose BMI of 25.8. Delivered 200J (device maximum) using a biphasic defibrillator. The attempt was unsuccessful. Switched to another manufacturer's biphasic defibrillator, and successfully cardioverted the patient from Afib to SR with one shock at 360J.
Zoll Medical Corporation; External Defibrillator	Device model#: M series	Attempted cardioversion of a patient whose BMI=45.1 using a 200J biphasic defibrillator (device maximum) and externally applied pressure. Unable to cardiovert. Changed to another manufacturer's device that goes to 360J biphasic. Successfully cardioverted from Afib with single shock at 360J biphasic. The Zoll M Series defibrillator was tested by our BioMedical Engineering dept and works to specification.
Zoll Medical Corporation; External Defibrillator	Device model#: M series	Attempted cardioversion on a patient whose BMI=43.4, delivering 200J with a biphasic defibrillator (device maximum). The attempt was unsuccessful. Obtained another biphasic defibrillator from another manufacturer - successfully cardioverted with 360J on the first shock. The Zoll M series 200 joule biphasic defibrillator was tested and works to specification.
Zoll Medical Corporation; External Defibrillator	Device model #: M Series	Attempted cardioversion on a patient whose BMI=28.9. The first shock was delivered at 120J biphasic, using externally applied pressure. There was no effect. Attempted again with 200J (the device maximum) using externally applied pressure. The patient remained in Afib. Obtained another manufacturer's 360J biphasic defibrillator and successfully cardioverted from Afib with one shock at 360J.
Zoll Medical Corporation; External Defibrillator	Device model #:AED Plus	When personnel went to use the AED, the AED had the correct indication device ready for use, applied pads; device said "acquiring DAT" then shut off. This was tried 2 times before emergency squad arrived less than 5 minutes from call. Device appeared to work normally on manufacturer supplied test unit, however, when attempting to use on a test patient, device failed. Manufacturer supplied information indicates batteries are bad, however testing of battery does not confirm. Manufacturer literature does not provide replacement time frame, however verbally the manufacturer says 5 years. Device has been performance inspected annually. Unknown if replacing batteries will resolve, waiting for new patient pad. The batteries were

		replaced and it did not solve the problem.
Medtronic Emergency Response Systems; External Defibrillator	Unknown	RN description of incident: During cardioversion, the defibrillator on the crash cart would not charge completely and wouldn't release shock. It started to charge but wouldn't complete the charge. A second defibrillator was brought in and the same thing happened, although it did charge and shock once. A third defibrillator was brought in and it worked fine. Both monitors were in sync mode at the time. CPD picked up crash cart defibrillator. Biomed picked up the Lifepak 12 defibrillator. MDs in room at time. Clinical Engineering evaluation: Biomed investigated the 2 machines and found nothing wrong with the machines themselves. This was determined to be a use error. Biomed stated that the verbal report was that a Medtronic Lifepak 12 was tried first, then a Lifepak 20. The user followed the incorrect sequence of events to program the defibrillators. The correct sequence is to: 1. Press "Energy Select" to choose energy level 2. Press "Charge" 3. Press "Shock". Instead, the user pressed "Charge", then "Energy Select." At this point the defibrillator will reset itself to zero (with no on-screen notification that it has done so), and will not shock. Education is recommended to new users of the defibrillators. Another option is to make stickers with directions on how to program the defibrillators, and place them on the machines. Also I recommend that the manufacturer, Medtronic, generate some kind of warning on the screen when it resets, for future models of the device.
Zoll Medical Corporation; External Defibrillator	Unknown	The patient was experiencing shortness of breath and exacerbation due to congestive heart failure. An ambulance was called to transport the patient to the nearest medical center. While in the ambulance, the nurse attempted to acquire a pre-hospital 12-lead electrocardiogram (ECG) using a Zoll monitor/defibrillator. The nurse was unable to get a reading. The monitor displayed the message "ECG Lead Off." The nurse checked the leads, verified that the leads were correctly placed and that there was good contact with the patient's skin. The nurse also verified that the cord was secure and correctly placed into the monitor end. A second attempt to obtain a 4 or 12 lead reading was unsuccessful. The patient was transported to the hospital and there was no negative

		outcome that resulted from the inability to monitor this particular patient's heart rhythm. The monitor/defibrillator was pulled from service and inspected by the Biomedical Engineering Department at the ambulance service's main hospital. The technician checked all the leads and sizes. The monitor passed tests in the 4 and 12 lead areas, as well as correctly sensed when the leads were off. The technician found no problems with the unit and returned it to service.
Zoll Medical Corporation; External Defibrillator	unknown	Unable to cardiovert with 2 attempts using Zoll M Series 200 joules biphasic device. Switched to another manufacturer's 360 joule biphasic device and cardioverted to NSR with single shock.
Zoll Medical Corporation; External Defibrillator	Device model #:M Series with Xtreme Pack	During an Electrophysiology Study, Sustained Polymorphic Ventricular Tachycardia was induced x2. Cardioversion was performed on this morbidly obese patient with a Zoll Defibrillator using 200 joules, biphasic. During the first episode the first of 2 shocks was ineffective at converting the rhythm. The second shock was effective. During the second episode the first and second of 3 shocks were ineffective at converting the rhythm. The third shock was effective.The energy was applied to the patient via hands free defibrillation pads. For the first event the pads were placed on the right upper chest and left apical area. The pads were replaced after the first event with new pads placed in the center of the chest, and center of the back.
Zoll Medical Corporation; External Defibrillator	Device model #: M Series	Patient with a six week history of Afib. Attempted to cardiovert using a Zoll M Series biphasic defibrillator. The first shock was at 100 joules, 2nd shock 200 joules with no affect on the rhythm. Changed to a different manufacturer's 360 joule biphasic device and cardioverted to a sinus rhythm with a single shock at 360 joules.
Zoll Medical Corporation; External Defibrillator	Device model #: M Series	Patient with afib; history included CAD s/p stent, CHF, cardiomyopathy, hyperlipidemia. Unable to cardiovert afib using Zoll biphasic M Series device 200 joules using counter pressure. Two attempts failed to convert the patient's rhythm. Changed to a different manufacturer's 360 joule biphasic device and cardioverted to sinus rhythm with one attempt.
Zoll Medical	Unknown	Failure to rescue a morbidly obese patient. A morbidly

Corporation; External Defibrillator		obese patient with non-ST elevation myocardial infarction status post cardiac catheterization, placement of stent x2 when he had a cardiac arrest. Ten defibrillation attempts were made with the Zoll M Series biphasic defibrillator at 200 joules (the max) and hands free pads anterior / posterior placement. Unable to rescue patient. Another manufacturer's BIPHASIC device was obtained and the patient was shocked x1 with 360 joules which resulted in conversion to a perfusing rhythm. The Zoll M Series defibrillator was fully checked after this event and is working to specification. This is the second event we have seen of a failure to rescue a morbidly obese patient with a biphasic device at the maximum capacity 200 joules.
Medtronic Emergency Response Systems; External Defibrillator	Device model #:Lifepak 20	Four attempts were made to defibrillate the patient. The first shock did not reach the patient, the second shock did. The third shock did not work and the fourth shock did. Print strip showed abnormal and sync off automatically on first and third attempts.
Zoll Medical Corporation; External Defibrillator	Device model #: M Series	Morbidly obese post-op patient had witnessed cardiac arrest. Underwent five unsuccessful rounds of ACLS medications and defibrillation using the Zoll M series biphasic defibrillator charged to 200 joules (the maximum) for pulseless ventricular tachycardia rhythm. The code team obtained and applied a different manufacturer's biphasic defibrillator that allows 360 joules defibrillation. The rhythm was captured and converted to normal sinus rhythm with a single biphasic shock at 360 joules.
Philips Medical Systems; External Defibrillator	Unknown	The staff attempted to defibrillate a patient using the hands free cable. When the staff member pressed the red buttons, the device did not fire. The staff then immediately utilized the paddles and the patient was successfully defibrillated.
Zoll Medical Corporation; External Defibrillator	Uknown	Patient with a near syncopal episode earlier, but no signs/symptoms at time of paramedic arrival. Pacer pads were placed on the patient, and staff were unable to pace. Patient had all four leads on, and each electrode had full contact with the patient's skin. All wires were properly hooked up to the monitor. All leads were in the appropriate spot/side and all leads (I, II, III, aVF, aVL and aVR) were showing the patient's rhythm on the defibrillator/monitor screen. The pads

		were also properly placed (anterior/posterior) and attached correctly at each junction. The monitor was put on "pacer" and the spikes that indicate the dialed rate (70) were noted in the monitor and the rate could be modified with the dial. When the mA dial was turned the monitor showed "0" and did not change when the dial was turned either way. The patient's rhythm did not change either and the patient denied feeling the "shocks" from being paced. Patient was transported to hospital as a "Code III" (emergency vs. routine) status due to the staff's concern that the patient's condition could deteriorate and the defibrillator would not work. There was no change in the patient's condition in route to the hospital. The defibrillator was removed from service and sent to Zoll for repair. Zoll reported that device is able to power up on battery and AC. The problem of being unable to adjust the pacer current was verified. The "Control to System Flex Cable" was reseated to remedy the problem condition. Software version 38.80 was installed. The device passed all final system level tests and was recertified to be used clinically.
Zoll Medical Corporation; External Defibrillator	Device model #: AED PLUS	A patient was at the hospital for an outpatient MD appointment. The patient was with family in the cafeteria and family witnessed the patient's arrest. ICU clinicians at scene began CPR and pulled the Zoll AED PLUS defibrillator to begin resuscitation. The AED powered up and went through the self test, advised "unit OK", then shut itself off. This occurred two times. CPR was continued throughout the period of getting the AED to complete its power up sequence. The Outpatient Code Team responded to scene with their defibrillator which was then used for the duration of the resuscitation effort. The first shock was delivered 8 minutes later. Resuscitation efforts were unsuccessful. The involved AED PLUS was reviewed by Biomed after these events. The AED PLUS is designed with a status indicator that shows a green check or red "X" to indicate if the machine has adequate battery strength. Prior to and after these events, this device had a green check showing. Page 4 of the Zoll AED PLUS Administrator's Guide "check mark indicates the unit passed its last self test and is ready for use". The AED PLUS device takes 10 Duracell batteries, type 123A (lithium manganese dioxide batteries). The batteries that were in this

		device when it failed had an expiration date of 2013. These batteries had been in the device since the device was deployed 2 yrs earlier. ========== Manufacturer response for Defibrillator, AED, AED PLUS
Zoll Medical Corporation; External Defibrillator	Device model #:PD1200	Patient with numerous dysrhythmias required defibrillation. Defibrillator passed test at the beginning of the shift. When attempted to defibrillate the patient, the defibrillator would not hold a charge or fire. The patient required chest compressions until another defibrillator could be used. After the incident, the defibrillator was tested again and it passed.
Zoll Medical Corporation; External Defibrillator	Device model #:M Series	The Zoll Defibrillator did not immediately power up. After two tries, power was obtained and the patient was shocked. Pt became stable and was transferred to the ICU.
Medtronic, Inc.; External defibrillator	Device model #:3202487-000	Unit failed during routine check. The unit was service by the manufacturer and they found a defective power board. After previous failures in our facility with these units, we have changed the way that the units are being checked. During the user test, we disconnect the power cord. This enables us to test the battery and the power board.
Medtronic, Inc.; External defibrillator	Device model #:3202487-015	Unit does not turn off. Power failure board failed. Unit did not have a software upgrade at that time.
Medtronic, Inc.; External defibrillator	Device model #: LP-20	While using the pacing function on the defibrillator, the service light came on. The defibrillator pacing function was operating properly and the unit stayed in use on the patient. When patient was discharged, the defibrillator was removed from service and the error log was checked. There was no error noted, but the service light stayed illuminated. The defibrillator was returned to the OEM (original equipment manufacturer) and the fault was verified. A defective component was found on the user interface PCB (printed circuit board). The defibrillator was fixed, tested, calibrated, adjusted, and then returned to service.
Zoll Medical Corporation; External Defibrillator	Device model #: R Series	Nurse was performing daily defibrillator test and pacer test. Pacer test failed. Device brought down to Biomed for evaluation. Biomed was able to duplicate the problem. When in Pacer Mode, cannot increase or decrease rate or output settings. Code Readiness Test

		Log - Failed. Also noticed error message 115.
Medtronic, Inc.; External defibrillator	Device model #: 3202487	Our facility has 36 Lifepak 20 defibrillators. Over the last few months we have had 5 units with a defective Power Module printed circuit board that enables the battery to be charged. One of the 5 units has had the circuit board replaced twice. When the units are unplugged to be used, the battery fails. We have noticed that the self-test is not totally reliable. If the Power Module PC board fails, and the unit remains plugged in to the AC mains power, the unit will pass the self-test and prints "Test Successful", however, when the unit is unplugged, the battery is depleted and the unit fails. This was discovered when a nurse was ready to use this device and the battery failed. The unit then had to be plugged in to the nearest outlet. The five units which have had failures of the Power Module PC board are listed in this report. All defibrillators in the facility have had the recall issues involving the batteries, and the software upgrade installed as necessary.
Zoll Medical Corporation; External Defibrillator	Device model #: R Series	After reviewing the summary report from this defibrillator, we do not see any evidence of pacer spikes nor increase of pace current. Although the Nurse did say she turned the pace current up. It appeared that there was a paced rhythm seen on the wall cardiac monitor in the room. The patient was being paced for Third Degree heart block.
Zoll Medical Corporation; External Defibrillator	Device model #: R Series	During the use of the pacing function, nurse said she attempted to use pacer but did not see pacer spikes. She then switched to another defibrillator and saw spikes.
Zoll Medical Corporation; External Defibrillator	Device model #: M Series	Equipment malfunction. Paramedics responded to 911 call for unresponsive person. Paramedics arrived, assessed the patient and connected a Zoll M Series Defibrillator. The patient received multiple shocks, medications, and ventilations. Initially, pacing was attempted. Staff was unable to perform pacing because they were unable to increase the pacer output from the default setting of 0 mA. However, there was no adverse outcome to the patient because of this malfunction. The defibrillator was pulled from service and the biomedical engineer verified that there was a malfunction with the pacer mA control knob. The control board was replaced and tested extensively. The defibrillator was placed back in service.

Zoll Medical Corporation; External Defibrillator	Device model #: M Series	Unit would not turn on for daily checks. Biomed verified it would not turn on either with AC or battery. The next day when demonstrating to Zoll rep, it worked fine. Zoll requested unit be sent back.
Zoll Medical Corporation; External Defibrillator	Device model #: M Series	Zoll unit did not stay on long when on battery. It worked fine after charging and after 1 week. Zoll requested unit be returned for replacement.
Zoll Medical Corporation; External Defibrillator	Device model #: M Series	Unit did not turn on for daily checks. Verified unit did have yellow LED ON, but would not come on for AC or DC.
Zoll Medical Corporation; External Defibrillator	Device model #: M Series	Unit would not turn on either with AC or DC. Reseated battery and unit tested okay. Could not find or access any error log inside unit. (Zoll says none available on M-series).
Zoll Medical Corporation; External Defibrillator	Device model #: M Series	Defib did not work on daily check. Would not come on when plugged into AC outlet with new or old battery. Yellow light was ON but green light never lit up.
Zoll Medical Corporation; External Defibrillator	Device model #: M Series	Out of box failure. Unit would not turn on.
Zoll Medical Corporation; External Defibrillator	Unknown	The internal defibrillator paddles did not seem to be discharging the right amount of joules. We switched to another set of defibrillator paddles and it still did not seem to be working properly. The anesthesia tech then brought another defibrillator into the room and it worked properly. The anesthesia tech took the other defibrillator out of room and gave it to biomed. Both the paddles and defibrillator were tested by a Biomed technician. The defibrillator tested fine with no problems found. However, while performing continuity test on the internal paddles, the technician found readings greater than 1 ohm.
Zoll Medical Corporation; External Defibrillator	Model #:PD 1200	Patient arrived at 2210 with stable vital signs; at 2400, rn hung iv antibiotic. At 2430, care partner found patient unresponsive, with no bp and no respiration. Cpr and code blue initiated. Monitor initially showed no palpable pulse in the presence of recordable cardiac electrical activity, pulseless electrical activity (pea). The defibrillator functioned and was plugged in. The defibrillator screen blanked out twice but then came

		back to reflect rhythm.patient arrived at 2210 with stable vital signs; at 2400, rn hung iv antibiotic. At 2430, care partner found patient unresponsive, with no bp and no respiration. Cpr and code blue initiated. Monitor initially showed no palpable pulse in the presence of recordable cardiac electrical activity, pulseless electrical activity (pea). The defibrillator functioned and was plugged in. The defibrillator screen blanked out twice but then came back to reflect rhythm.
Medtronic; external defibrillator	Unknown	Code blue full arrest cpr in progress, acls protocol in place, @ 0732 epi and other acls drugs being admitted via iv. At 0743, pt paced with capture, 0747 attempted to pace again but did not capture this time. Pt had been in full arrest at all times, no pulse ever noted. Equipment removed from room and biomed notified. Equipment removed by biomed.
Philips medical systems; external defibrillator	Model #:m4735a	Nurse was doing shift check on defibrillator. The machine was hooked up to the patient. The nurse conducting the test asked patient nurse if she could test the equipment. She was told to go ahead. The nurse checking the equipment did not see the alert that came up saying "verify test load is on" and she could not see that the patient was connected and ready for pacing should it be required. She pushed the button and the patient felt a sensation. There was no adverse outcome to the patient.
Zoll medical corporation; external defibrillator	Unknown	Pt coded. When attempted to use defibrillator, machine did not deliver shock. After attempting to get machine to work, another machine was obtained. Pt expired.
Physio-control, inc.; external defibrillator	Unknown	Patient presented to the emergency department in cardiac arrest (unresponsive and cyanotic). Family unsure how long the patient had been in cardiac arrest when arrived at ed. Physio control lifepak 9p defibrillator would not deliver after three attempts. Defibrillator had power but would not fire. Different defibrillator was used at this point. Small delay in changing defibrillator. Unsure if the small delay in changing defibrillator caused patient harm. Patient did expire after 45 minutes of critical care and resuscitation attempts. Investigation showed no user error. Defibrillator was test fired and worked appropriately. All other issues were investigated that may have caused defibrillator to not fire and nothing

		was found. Bio-med inspection did find that battery needed to be replaced but at the time defibrillator was used on patient ac power was being used and the battery would not have been an issue.
Medtronic; external defibrillator	Model #: 3202487-015	Patient found unresponsive. Medtronics aed and quick combo pads taken from crash cart. The electrodes did not dissipate the charge. Another set of pads were obtained in next unit and exchanged. The packaging on the two became a puzzle as only one packaging found, and it is not known if it belongs to the non-working set or the set used. Patient responded, but expired the next afternoon from his illness.
Zoll medical corporation; external defibrillator	Model#: m series	Daily checks revealed "test failed" message. Also failed in biomed shop after swapping out old and installing new battery. Unit's battery was placed in another defibrillator unit and it worked fine.
Zoll medical corporation; external defibrillator	Model #:r series	During cpr, pad tore at cpr puck causing the pad to raise and create an arch during defibrillation, resulting in burn to pt.
Medtronic; external defibrillator	Model #: lp20	During a code, the lifepak was charged, but did not release a shock. The machine then shut down. The machine had to be plugged in, it then worked fine and delivered a shock. After the code, a self test was performed and it passed. Biomed repair form completed. Biomed did check the log with the help of medtronic and no error codes were found. Most recent pm was done one month ago. Patient survived the code and is still a patient at our facility. The manufacturer came and retrieved further logs on the device and it appears that once it was charged to shock the patient the off button was hit.
Zoll medical corporation; external defibrillator	Unknown	Zoll battery read over charge removed-battery and hot liquid poured out the end onto the nurse.
Zoll medical corporation; external defibrillator	Model #: pd 1200	Patient was being defibrillated and spark caused small fire resulting in second degree burns to patient's chest. Oxygen was in use at the time.

Additional Information:

AED Programs Q & A." American Heart Association. American Heart Association, http://www.americanheart.org/[51]

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Summary of MedSun Reports Describing Adverse Events With Troponin Assays

Print Item
E–mail Item

Troponin assays are clinical tests used on patients suspected of suffering from a cardiac episode or from other heart damage. Cardiac troponins are highly sensitive specific biochemical markers of myocardial cell necrosis. In the case of a myocardial infarction or infiltrative/inflammatory response, myocyte death causes these troponin levels to rise and fall, providing a key indicator of a patient's cardiac health. Troponin tests are often done in conjunction with other cardiac biomarker exams (CK-MB or myoglobin), but because troponin fluctuations are specific to cardiac damage they are often the preferred test method of clinicians (1, 2, 3).

Over the past 5 years, MedSun has received 25 adverse event reports associated with troponin assays. Five manufacturers are mentioned in these reports: Siemens Medical Solutions (10), Dade-Behring, Inc (7), Bayer Healthcare LLC (6), Picis Inc (1), and Beckman Coulter, Inc (1). The reports were submitted by 9 hospitals between January, 2004 and July, 2009.

The reported device problems were:
• Falsely Elevated Result (12)
• Poor Precision/Inconsistency (8)
• Falsely Depressed/Negative Result (2)
• Sensor Malfunction (1)
• Defective Component (1)
• Device Misidentified Patient (1)

During this time period there were no reported deaths associated with these devices. Further procedures (catheterization, extra diagnostics, and/or thrombolytic agent administration) were performed on four patients based in part on false readings from these devices.

A total of at least 58 patients were affected in the events related to the reports. All of these patients were older than 21 years of age. Of the reports that listed patient gender, a total of 22 reports involved female patients and a total of 33 reports involved male patients.

These MedSun reports contributed to FDA awareness of the device problems.
FDA follow-up with the manufacturers may or may not have contributed to the following recalls.

The following is a table describing the recall history if troponin sensing devices dating from 2003 to 2009.

Table of Device Recalls

Product Name	Manufacturer/Recalling Firm	Recall Class	Date Posted	Description
AxSYM Troponin-I ADV Reagent Pack, Abbott Laboratories, Abbott Park, IL 60064; AxSYM Troponin-I ADV ...	Abbott Laboratories	2	Apr-15-2009	Defective caps: Customers have observed reagent bottles not opening appropriately, which could lead to a probe crash on the instrument.
ADVIA Centaur TnI-Ultra Assay, Troponin Immunoassay, 500 tests - Part/Catalog # 02790309, and 100 te...	Siemens Medical Solutions Diagnostics	2	Jun-05-2008	Incorrect results: Falsely elevated Troponin values have been reported which are inconsistent with the patient's clinical picture and test negative by other Troponin assays.
ARCHITECT STAT Troponin-I Reagent; list numbers 2K41-20 (400 test kit), 2K41-25 (100 test kit) and 2...	Abbott Laboratories MPG	1	Jun-14-2007	False Negative Results : The analytical sensitivity claim of less than or equal to 0.01 ng/mL (ug/L) might not be met for all lots of Architect STAT Troponin-I reagents, thus false negative results may occur with negative results less than 0.1 ng/mL
ARCHITECT STAT Troponin-I Reagent Kit, list 2K41-20; each 400 test kit contains 4 bottles each of mi...	Abbott Laboratories MPG	2	Feb-14-2006	There has been an increase in customer complaints observed for failure to calibrate

				or inability to generate patient result errors.
AxSYM Troponin-I Reagent Kit, list 3C29-20, 100 test kit; Abbott Laboratories, Abbott Park, IL 60064	Abbott Laboratories HPD/ADD/GPRD	2	Jul-20-2004	An increase in complaints of higher than normal patient results, some from the healthy population range to above the diagnostic cutoff for an Acute Myocardial Infarction.
Vitros Immunodiagnostic Products TROPONIN I Reagent Packs, (Lot 1110 and 1130 REF #194 9882 and Lo...	Ortho- Clinical Diagnostics	1	Jul-20-2004	Random occurrence of false positive test results.
Elecsys Troponin T STAT; catalog number 2017423	Roche Diagnostics Corp.	2	May-29-2003	Hemoglobin interference limitation revised downward; hemolyzed samples may result in false negative results.

The following is a table showing the 25 adverse event reports received into MedSun for troponin assays since 2004. Note: Centaur devices were once manufactured by Bayer Healthcare, but are now products of Siemens Medical Solutions. These systems will appear under both manufacturers in this adverse events table.

Adverse Event Table

Manufacturer	Model	Event description
SIEMENS MEDICAL SOLUTIONS DIAGNOSTICS	DADE RXL	ER physician called and notified the lab director that they thought they were having trouble with our troponins. Troponin i results were falsely elevated, resulting in a patient being transferred from our facility to

		another for cardiac catherization. Upon arrival at other facility, troponin i performed with a negative result being obtained. Cardiac catherization not performed. During the resolution process, it was discovered a precision problem with the instrumentation existed and had the instrument decontaminated. Recalibration of the assay was performed and quality control was acceptable. No shifts in quality control were noted prior to notification of a suspected problem by the ER physician. Patients were repeated on alternate analyzer and amended reports were issued. Troponin i testing was discontinued on patients until problem was resolved
SIEMENS MEDICAL SOLUTIONS USA, INC.	IMMULITE 2000	After being notified by an endocrinologist that one of their patients had "unusual" results for free t4 and tsh, we repeated the tests on the original sample in question the next day and found that the originally reported results were incorrect. The physician was notified of the corrected results. During further investigation we found nothing unusual about the samples. There were no related error messages on the immulite 2000 instrument, and no noticeable differences with anything at the time of repeating the tests. The instrument manufacturer's technical support was called the same day, but no immediate cause for the error was found. Technical support downloaded information from our instrument and told us that they would look into the matter. Two days later the technical service engineer relayed to the physician that there were numerous error messages contained in a log file that we should have been alerted to but were not. The engineer also found several parts that needed to be replaced and could have produced the erroneous results. These parts were replaced and additional quality control checks were performed. We are aware of only one patient that had unnecessary follow-up procedures started due to initial incorrect

		results.
SIEMENS MEDICAL SOLUTIONS USA, INC.	CENTAUR	Our technologist noticed an unusual pattern of results for troponin for patients from the E.D.. They called the ED and notified them of their suspicions, and told them she was going to investigate a potential instrument malfunction. They told the E.D. staff that they would notify them of their investigational outcome. The technologist identified the problem as a depletion of a wash 1 solution that caused the instrument to report falsely elevated troponin results on three patients. They corrected the instrument issue and re-ran the patient samples on our other instrument and notified the ED of the corrected results. The technologist reviewed and re-ran.
BECKMAN COULTER, INC.	UNICEL DXI 800	There was a hole in the peristaltic pump tubing on a Beckman Coulter Unicel dxi 800 that was causing falsely elevated troponin levels for multiple patients. No errors or flags were given on the instrument to alert the lab technicians to the problem. The results were auto-filed, and based on the falsely elevated troponin levels, two patients were admitted to the coronary care unit and scheduled for cardiac cath procedures the next day. One patient had a hip surgery delayed, and the other had their discharge delayed. Beckman coulter has found that a defective pump is the problem and is causing the tubing failures. This defective pump affected at least one of the wash cycles causing the elevated troponin levels. This report is similar to another report submitted earlier this year on the same analyzer. There was a defined period in which these pumps were manufactured that where the bearings that roll the tubing were tipped slightly, causing friction or wear on the tubing.
SIEMENS MEDICAL SOLUTIONS USA, INC.	BAYER ADVIA CENTAUR IMMUNOASSAY SYSTEM	Centaur instrument error resulted in an incorrect troponin value being reported. The specimen collected gave a result of 0.23. The result was called to the nurse. Another

		troponin collected approximately seven hours later gave a result of less than 0.02. Both specimens were retested and the results of both specimens were less than 0.02. The earlier test results were deleted from the computer and the nurse was notified. Siemens will be notified about the error.
SIEMENS MEDICAL SOLUTIONS DIAGNOSTICS	CENTAUR	The immunoanalyzer gave erroneous results on several patients. The error was found the next day when performing the quality check. A corrected report was issued. The instrument was removed from service for troubleshooting and repairs. Generally, there was no patient harm. In one case, a patient was admitted based on the incorrect results. The patient was discharged home the following day.
BECKMAN COULTER, INC.	UNICEL DXI 800	Instrument, two days prior to incident, was giving multiple strange errors. Service was called and errors were resolved after two days of service and part changes. QC was run and was within acceptable ranges. Service call was closed. QC was run again six hours later and all results were not within acceptable limits. No errors were displayed by the instrument until that time. Random patients were retested and all results did not reproduce. All specimens between the service call and the QC were retested on another similar dxi instrument and corrected results needed were generated on all patients. Service on the following day found a split peristaltic pump tubing on aspirate probe 3. No instrument errors were displayed during this time frame. Manufacturer response for immunoassay, unicel dxi 800: service engineer replaced broken tubing.
SIEMENS MEDICAL SOLUTIONS USA, INC.	BAYER ADVIA CENTAUR IMMUNOASSAY SYSTEM	Troponin results were reading high on several patients. Results were repeated on another analyzer and corrections were called in. Patient 1: original result was 0.09. The repeat result was 0.02. Patient 2: original result was 0.08. The repeat result was less

		than 0.02. Patient 3: original result was 0.08. The repeat result was less than 0.02. Patient 4: original result was 0.10. The repeat result was 0.04. Patient 5: original result was 0.08. The repeat result was 0.02. Patient 6: original result was 0.07. The repeat result was 0.02. Patient 7: original result was 0.07. The repeat result was less than 0.02. Patient 8: original result was 0.09. The repeat result was less than 0.02. Nothing was done to these patients because of the incorrect results. Siemens service was called in to fix bleach leak problem, in which valves had to be replaced. Manufacturer response: ultra troponin test gives occasional high fliers. System performance kits have been run several times with excellent results and thousands of multidill 11 have been run to check the low end precision of ultra troponin with very good results. Visual protocol showed a problem with aspirate probe 3. With drawer pulled out slightly there was no problem. We found the pinch tubing routing to be a problem when the drawer was pushed completely in. We re-dressed the tubings and tested with no further problem. We also noted crimped tubing between valves 66 and 77 causing low water delivery to the aspirate manifold but this was a recent fault. During the remaining check out we realigned the incubation ring and all probes and rerouted some tubing on reagent heater coils 1 and 2. We ran background checks with good results. We ran another svk procedure and got excellent results. We recalibrated two different lots of tnlultra and ran QC in reps and over 100 multidill 11 with excellent results. We ran 17 samples from the other centaur in duplicate and found the accuracy between systems to be excellent. We ran remaining qc and all were in.
SIEMENS MEDICAL SOLUTIONS USA,	BAYER ADVIA CENTAUR IMMUNOASSAY	There have been six reports of incorrect troponin values released. The incorrect values were obtained using the same

INC.	SYSTEM	chemistry analyzer. 1) troponin imprecision on Bayer Centaur resulted in reporting of incorrect troponin value of 0.07. The repeat on another analyzer was 0.03. 2) troponin imprecision on Bayer Centaur resulted in reporting of incorrect troponin value of 0.08 and 0.39. The repeat on another analyzer was 0.02. 3)troponin imprecision on Bayer Centaur resulted in reporting of incorrect troponin value of 0.08. The repeat on another analyzer was 0.02. 4) troponin imprecision on bayer centaur resulted in reporting of incorrect troponin value of 0.30. The repeat on another analyzer was 0.13. 5) troponin imprecision on bayer centaur resulted in reporting of incorrect troponin value of 0.15. The repeat on another analyzer was 0.09. 6) troponin imprecision on Bayer Centaur resulted in reporting of incorrect troponin value of 0.028 and 0.09. The repeat on another analyzer was less than 0.02. In all six cases the corrected report was called to the rn. The results were corrected in the computer with a note of explanation. There was no patient intervention due to the incorrect lab results. The company was called and service came to fix the problem. Service thinks that air was trapped in the lines after the daily cleaning. We do not know how that occurred or how to prevent it in the future. The quality control for the troponins worked and the technician had no reason to doubt the operation of the instrument for the troponin assay.
SIEMENS MEDICAL SOLUTIONS USA, INC.	BAYER ADVIA CENTAUR IMMUNOASSAY SYSTEM	Incorrect troponin results were reported on two patients. 1) poor instrument precision on Bayer Centaur resulted in an incorrect troponin to be released on the patient. The floor was notified of the incorrect result. Nothing was done to the patient as a result of the incorrect result. The result was changed in the computer with a note of explanation. 2) an incorrect result for troponin was released due to bayer centaur instrument poor precision. The patient had a

		previous positive result. Nothing was done to the patient as a result of the incorrect troponin result. The result was changed in the computer with a note of explanation. Siemens is currently working on this issue with us. Results between 0.08 and 0.50 are being repeated. If the result is within 50% of the previous and within 12 hours of the last result it releases automatically.
SIEMENS MEDICAL SOLUTIONS USA, INC.	BAYER ADVIA CENTAUR IMMUNOASSAY SYSTEM	There have been 4 reports of incorrect troponin results. Patient 1: incorrect troponin result was released due to a Centaur instrument error. The results were repeated on another instrument and the correction called to the unit. The patient had a previous positive result. The patient received no treatment based on this incorrect troponin result. Siemens was notified of the error. Results between 0.08 and 0.50 are repeated automatically. The tech should have looked at the precision prior to releasing results. E-mails and lab meetings included this information earlier this week. Patient 2: instrument and tech error in releasing a troponin result. The first result released was 0.13. Upon repeating of test, the result was 0.04. The Centaur instrument reported the incorrect result for this test. The company, siemens, was notified of the error. The tech failed to check the repeat prior to releasing the result and released the incorrect result. The tech will be counseled concerning this error. There was no adverse reaction to the patient as a result of this incident. Patient 3: an incorrect troponin result was released on this patient due to a centaur instrument error. The results were repeated on another instrument. The unit was notified of the error and the corrected result. Siemens was notified of the error. It is a negative troponin, but the precision did not look good. Results between 0.08 and 0.50 are repeated automatically. The tech should have looked at the precision prior to releasing results. E-mails and lab meetings

		included this information earlier this week. Patient 4: Centaur instrument error which caused and incorrect troponin result to be released on this patient. The results were repeated on another instrument and the unit was notified. No treatment had been given to the patient as a result of the incorrect troponin error. Siemens was notified of the instrument error. We will follow up with all employees to make sure that they understand the protocol.
BAYER HEALTHCARE LLC	ADVIA CENTAUR IMMUNOASSAY SYSTEM	There have been four reports of incorrect troponin results in a three week period all using the same chemistry analyzer. Patient 1: the troponin result was reported as 0.18 and when it was retested it was really 0.04. The error was detected because the result was not consistent with previous results. The results had been released. The patient was admitted with chest pain/shortness of breath and increased troponin level. The patient was given aspirin and heparin. The patient had an echo test and was scheduled for a cath procedure. The doctor was consulted. The unit was notified when the error was detected. The error occurred on the Bayer Centaur analyzer and the company was notified. The analyzer was taken out of service. Patient 2: troponin result was reported as 0.15 and when repeated was really 0.06. The error was discovered because the result was not consistent with previous results. The incorrect value was reported and a cardiologist consulted but no treatment was administered as a result. The error occurred on the Bayer Centaur analyzer. The company was called and the instrument was taken out of service. The unit was notified of the error. Patient 3: erroneous troponin result of 0.10 ng/ml was released to the emergency department. Subsequent troponin result was <.2 ng/ml. When the first specimen was pulled and repeated, the result was <0.02. The nurse was notified of the error. The patient was admitted with

		shortness of breath and COPD, not due to the troponin result. The centaur was the instrument involved in the error. The error was reported to the company. Patient 4: elevated troponin result was released due to instrument error. The error was discovered when another specimen on this patient was tested. The result of the second specimen was 0.02. The first specimen was retested and found to be <0.02. The nurse was notified of the error and the result was corrected. The patient was not treated for the elevated troponin result first reported. Bayer has been in
BAYER HEALTHCARE LLC	ADVIA CENTAUR IMMUNOASSAY SYSTEM	We have had two recent events where troponin results were reported incorrectly. In the first incident, the troponin results were reported as 0.18. The repeat result was 0.09. The patient had previous results of 0.10 and 0.10. The nurse was notified of the correction of the result. In the second event, troponin result was reported as 0.48. The repeat of this test was 0.02. The nurse was notified of the change in result. One of the patient's had received heparin and aspirin and a cardiologist had been called for consultation. No treatment had been initiated on the other patient. Bayer was notified and service was scheduled. No more patients were tested on this instrument until after service. Bayer's field service engineers changed the bleach valves and wash block on the instrument. The wash block was leaking and the engineers noted the leak could cause carryover from the bleach that is used to do the monthly cleaning. The manufacturer will be in next week to do more crossover studies to make sure that this actually fixed the problem. The manufacturer recalibrated the system and ran quality control and all worked fine.
BAYER HEALTHCARE LLC, DIAGNOSTICS	ADVIA CENTAUR IMMUNOASSAY SYSTEM	Incorrect troponin result was released on three patients due to poor precision on the Bayer Centaur chemistry instrument. Patient 1 - a troponin result of 0.62 was released.

DIV.		The next troponin result was 0.06. The first specimen was repeated and the result was less than 0.02. There was no procedure performed on the patient as a result of the incorrect troponin result of 0.62. The patient was in CV (cardiovascular) recovery and a cath scheduled before the false positive troponin was released. Patient 2 - the specific troponin values were not provided. The patient was given nitroglycerine ointment due to the incorrect result. Patient 3- the specific troponin values were not provided and there is no follow-up information on this patient. Bayer was notified. These are new instruments. Bayer has been very willing to work with us on resolving this issue with their instrument. Bayer has sent in reagents for us to run these samples in duplicate for a week to actually watch every test we are releasing. We have had one test that was discrepant out of over five hundred and it did not happen on the instrument that we have had issues with. The result of that one test did not make a clinical difference in the patient's care. Previous to sending the reagents they have sent field service engineers out to work on the instrument. They have not found a cause for the discrepant results as of yet. They sent questions out on their list server to see if anyone else is experiencing this problem and what sample type they are using. We are working on this end to make sure that the pre-analytical piece of testing is what it should be. We are looking at specimen integrity and spin times of the sample.
BAYER HEALTHCARE LLC DIAGNOSTICS DIV	ADVIA CENTAUR	There were instrument problems with the Bayer centaur chemistry analyzer that were not discovered before incorrect results were released. Incorrect results were released on 9 patients. Quality control was all within range. There was no indication of a problem until delta checks were alerting us
DADE BEHRING,	DIMENSION RXL	Rxl chemistry instrument reported critical

INC.	CHEMISTRY INSTRUMENT	results of na 122, k 2.7 and chl 90. Instrument repeated since values were critical. Repeat results were na 135, k 3.1 and chl 103. Dade could not explain this error except their usual specimen integrity. The instrument reported three incorrect results.
DADE BEHRING, INC.	RXL	Troponin level reported on instrument was 0.15, 0.00 and 0.01. When run again, results were 0.41, 0.00 and 0.01. Tests were repeated on a different instrument and were 0.03, 0.03 and 0.05. Dade was notified of this issue. There was no patient harm/injury invovled.
DADE BEHRING, INC.	DIMENSION RXL CHEMISTRY INSTRUMENT	A troponin i was reported on an emergency room patient as negative. When repeated, the result was positive-0.63ng/ml. Dade Behring was notified and service was called to evaluate the instrument and reagent. The patient was treated appropriately and there was no injury due to the incorrect result.
BAYER HEALTHCARE, LLC	BAYER CENTAUR	Erroneous troponin results reported in 28 patients. Technician got suspicious and re-ran troponin levels and tried to calibrate the machine; however calibration of the device failed. All tests were stopped and all physicians notified that lab results could be incorrect. One patient was sent for cath lab procedure; however the procedure was stopped before it began. Several patients were given heparin that was not needed and treatment was discontinued when correct results were received.
DADE BEHRING, INC.	DIMENSION RXL CHEMISTRY INTRUMENT	Troponin test was run in triplicate produced the following results: 0.00, 3.34 and 0.01. Dade Behring was notified of results. Ri probe that had been changed the day before this incident was changed again and drain was cleaned. These results are clinically significant however,
DADE BEHRING, INC.	DIMENSION RXL H/M	There was no treatment initiated to the patient due to erroneous results.
DADE BEHRING, INC.	DIMENSION RXL CHEMISTRY	The instrument gave an erroneous results, with no indication of a problem.

	INSTRUMENT	
BAYER HEALTHCARE, LLC	CENTAUR	Centaur equipment was being used to obtain troponin level on patients. A faulty valve caused intermittent falsely elevated troponins of approximately 30 patients. Of the 30 patients, 14 received faulty readings. All 14 patient's cases were reviewed. One patient had a stent placed, but the procedure was considered necessary even after the review of the results.
DADE BEHRING, INC.	DIMENSION RXL CHEMISTRY INSTRUMENT	Rxl instrument reported troponin i as 0.03ng/ml (nanogram/ml) when result was really 3.10ng/ml. 0.35ng/ml is the cutoff for risk stratification of an acute myocardial infarction. Incorrect results were not released. No pt injury.
PICIS, INC	ED PULSECHECK	Lab results were reported for the wrong patient: A patient was admitted to the ED with kidney pain. The Physician's Assistant assigned to the patient noted that troponin levels were reported on this patient, but were not ordered. The physician's assistant notified the lab immediately of the error. The troponins had actually been drawn for another patient admitted to the ED on the same day for a CVA. There was no delay in treatment for that patient. Investigation revealed that the Laboratory results produced in Cerner Laboratory Software system were resulted correctly, and the Siemens HIS Software system also resulted correctly. However, when resulted out in the Picis ED Pulsecheck (IBEX) system, the results were for the wrong patient.

Other FDA articles and notices of interest related to troponin analyzers include:

Safety Tip (for laboratorians and clinicians):
Troponin: What Laboratorians Should Know to Manage Elevated Results
http://www.fda.gov/MedicalDevices/Safety/AlertsandNotices/TipsandArticlesonDeviceSafety/ucm109362.htm

Additional Information:

1. Lab Tests Online: Troponin
http://www.labtestsonline.org/understanding/analytes/troponin/test.html[53]

2. Antman, Elliott M., Tanasijevic, Milenko J., Thompson, Bruce, Schactman, Mark, McCabe, Carolyn H., Cannon, Christopher P., Fischer, George A., Fung, Anthony Y., Thompson, Christopher, Wybenga, Donald, er al. Cardiac-Specific Troponin I Le
http://content.nejm.org/cgi/content/abstract/335/18/1342[54]

3. JE Adams, 3d, GS Bodor, VG Davila-Roman, JA Delmez, FS Apple, JH Ladenson, and AS Jaffe Cardiac troponin I. A marker with high specificity for cardiac injury
http://circ.ahajournals.org/cgi/content/abstract/88/1/101#otherarticles[55]